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และวารสารเวชศาสตร์เขตเมือง

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คำชี้แจงการส่งบทความ

วชิรเวชสารเป็นวารสารการแพทย์ของคณะแพทยศาสตร์-วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช เริ่มพิมพ์ครั้งแรกในปีพ.ศ. 2500 และพิมพ์เผยแพร่อย่างสม่ำเสมอ ปีละ 6 ฉบับ ทุก 2 เดือน (มกราคม-กุมภาพันธ์, มีนาคม-เมษายน, พฤษภาคม-มิถุนายน, กรกฎาคม-สิงหาคม, กันยายน-ตุลาคม และพฤศจิกายน-ธันวาคม) และมีฉบับเพิ่มเติมปีละ 1 เล่ม เพื่อตีพิมพ์ผลงานที่นำเสนอในงานประชุมวิชาการของมหาวิทยาลัยหรือของคณะ โดยมีวัตถุประสงค์เพื่อเผยแพร่ผลงานวิจัยในรูปแบบของนิพนธ์ต้นฉบับ รายงานผู้ป่วยและบทความวิชาการทางการแพทย์ รวมทั้งผลงานวิชาการด้านแพทยศาสตรศึกษาและวิทยาศาสตร์สุขภาพ

วชิรเวชสารมุ่งเน้นความรู้เกี่ยวกับเวชศาสตร์เขตเมือง ได้แก่ วิทยาศาสตร์พื้นฐานและวิทยาศาสตร์การแพทย์คลินิก รวมถึง ระบาดวิทยา สมุฏฐานวิทยา พยาธิกำเนิด การวินิจฉัย และการดูแลรักษาโรค อันเกี่ยวข้องกับสุขภาพของประชาชนในเขตเมือง

บทความที่ส่งมาตีพิมพ์จะได้รับการกลั่นกรองโดยผู้ทรงคุณวุฒิที่มีความเชี่ยวชาญในสาขานั้น ๆ อย่างน้อย 2 ท่านในแง่ของความเหมาะสมทางจริยธรรม วิธีการดำเนินการวิจัย ความถูกต้อง ความชัดเจนของการบรรยายในการนำเสนอ รายชื่อของผู้นิพนธ์และผู้กลั่นกรองจะได้รับการปกปิดโดยกองบรรณาธิการก่อนส่งเอกสารไปให้ผู้เกี่ยวข้องทั้ง 2 ฝ่าย กองบรรณาธิการขอสงวนสิทธิ์ในการตรวจแก้ไขบทความก่อนพิจารณาตีพิมพ์ ทั้งนี้ข้อความและความคิดเห็นในบทความนั้น ๆ เป็นของเจ้าของบทความโดยตรง

บทความที่ส่งมาต้องไม่เคยพิมพ์ที่ใดมาก่อน และไม่อยู่ระหว่างการพิจารณาเพื่อพิมพ์ที่ใด ๆ ยกเว้นในรูปแบบบทคัดย่อหรือเอกสารบรรยาย กรณีที่บทความได้รับการพิมพ์ในวชิรเวชสารแล้ว ผู้นิพนธ์จะได้รับสำเนาพิมพ์ 30 ฉบับ ภายหลังหนังสือเผยแพร่เรียบร้อยแล้ว และผู้นิพนธ์ไม่สามารถนำบทความดังกล่าวไปนำเสนอหรือพิมพ์ในรูปแบบใด ๆ ที่อื่นได้ ถ้าไม่ได้รับคำอนุญาตจากวชิรเวชสาร

หลักเกณฑ์ทั่วไปในการเตรียมและส่งต้นฉบับ

การส่งต้นฉบับ ให้ส่ง 3 ชุด พร้อม diskette หรือแผ่น CD หรือส่งทางระบบ online (https://tci-thaijo.org/index.php/VMED และ http://thailand.digitaljournals.org/index.php/VMJ/) หรือส่ง ทางระบบ online (https://tci-thaijo.org/index.php/VMED และ http://thailand.digitaljournals.org/index.php/VMJ/) พร้อมรายการตรวจสอบบทความ และจดหมายเพื่อขอพิมพ์ ไปยังกองบรรณาธิการ ซึ่งจดหมายนี้ต้องมีชื่อ ที่อยู่ หมายเลขโทรศัพท์ โทรสาร และ email address ของผู้นิพนธ์ระบุว่า ผู้นิพนธ์ท่านใดเป็นผู้รับผิดชอบหลัก และต้นฉบับนั้นเป็นบทความประเภทใด (นิพนธ์ต้นฉบับ รายงานผู้ป่วย หรือบทความวิชาการ) รวมทั้งต้องมีข้อความว่าผู้นิพนธ์ทุกท่านได้อ่านและเห็นด้วยกับต้นฉบับนั้น และเชื่อว่าต้นฉบับนั้นรายงานผลตรงตามผลการวิจัยที่ได้ศึกษา และต้นฉบับนั้นไม่เคยพิมพ์ที่ใดมาก่อนและไม่อยู่ระหว่างการพิจารณาเพื่อพิมพ์ที่ใด ๆ ในกรณีที่เรื่องนั้นเคยพิมพ์ในรูปบทคัดย่อ หรือวิทยานิพนธ์ หรือเคยนำเสนอในที่ประชุมวิชาการใด ๆ จะต้องแจ้งให้กองบรรณาธิการทราบด้วย สำหรับเรื่องที่ทำการศึกษาในคน จะต้องมีหนังสืออนุญาตจากคณะกรรมการจริยธรรมการศึกษาวิจัยในมนุษย์แนบมาด้วย

ต้นฉบับจะเป็นภาษาไทยหรือภาษาอังกฤษก็ได้ ถ้าเป็นภาษาไทยควรใช้ภาษาไทยให้มากที่สุด ยกเว้นคำภาษาอังกฤษที่ไม่มีคำศัพท์นั้น ๆ ในภาษาไทยหรือแปลแล้วได้ใจความไม่ชัดเจน ภาษาอังกฤษที่ใช้ให้ใช้ตัวพิมพ์เล็กทั้งหมดยกเว้นชื่อเฉพาะที่ให้ใช้ ตัวพิมพ์ใหญ่เฉพาะอักษรต้น ตัวเลขใช้เลขอารบิก เนื้อหาควรมีความกระชับโดยมีความยาวเหมาะสมกับการพิมพ์ การพิมพ์ต้นฉบับให้ใช้ font Cordial New 16 พิมพ์หน้าเดียวบนกระดาษ A4 และพิมพ์บรรทัดเว้นบรรทัด โดยเว้นระยะห่างจากขอบทั้ง 4 ด้านไม่น้อยกว่า 1 นิ้ว โดยไม่ต้องปรับขอบด้านขวาให้ตรงกัน

รายการตรวจสอบบทความ (checklist guideline)

ผู้นิพนธ์ต้องตรวจสอบต้นฉบับที่จัดเตรียมให้ครบถ้วนถูกต้องตรงตามรายการตรวจสอบบทความ และส่งมาพร้อมกับบทความ บทความที่ส่งมาโดยไม่มีใบรายการตรวจสอบบทความ หรือมีไม่ครบ หรือไม่ถูกต้องตามที่กำหนดไว้จะถูกส่งกลับก่อนการดำเนินการใด ๆ ทั้งสิ้น ผู้นิพนธ์สามารถ download รายการตรวจสอบบทความชนิดต่าง ๆ ได้จาก website ของวชิรเวชสาร (http://www.vajira.ac.th/vmj)

คำแนะนำในการเขียนบทความ

การวิจัยแบบสุ่ม การวิจัยเพื่อการวินิจฉัยโรค และการวิจัยเชิงสังเกต ควรจะตรวจสอบความถูกต้องครบถ้วนของเกณฑ์ตามแนวทางของ Consort 2010 checklist, STARD checklist และ STROBE checklist ตามลำดับ ผู้นิพนธ์สามารถอ่านรายละเอียดเพิ่มเติมได้ผ่านทาง website ของวชิรเวชสาร

ผู้นิพนธ์ควรเตรียมบทความตามแนวทางการเขียนบทความทางวิทยาศาสตร์สุขภาพของคณะบรรณาธิการวารสารนานาชาติ (International Committee of Medical Journal Editors) ซึ่งมีรายละเอียดทาง website http://www.icmje.org/recommendations/ ดังจะสรุปไว้เป็นแนวทางดังต่อไปนี้ คือ บทความที่ส่งเพื่อพิจารณาตีพิมพ์ ควรเขียนเรียงตามลำดับดังนี้ ชื่อเรื่องและผู้นิพนธ์ บทคัดย่อ เนื้อหาหลัก กิตติกรรมประกาศ เอกสารอ้างอิง

1. ชื่อเรื่อง (title) ควรตั้งชื่อเรื่องให้กะทัดรัด ได้ใจความชัดเจน ไม่ใช้ตัวย่อใด ๆ ชื่อเรื่องภาษาไทยให้ใช้ภาษาไทยทั้งหมด ภาษาอังกฤษที่มีในชื่อเรื่องให้แปลเป็นไทย ถ้าแปลไม่ได้ให้เขียนทับศัพท์ ถ้าเขียนทับศัพท์ไม่ได้ให้เขียนเป็นภาษาอังกฤษด้วยตัวพิมพ์เล็กยกเว้นชื่อเฉพาะที่ให้ใช้ตัวพิมพ์ใหญ่เฉพาะอักษรต้น ชื่อเรื่องภาษาอังกฤษให้ใช้ตัวพิมพ์ใหญ่ในอักษรต้นตัวแรกของทุกคำ ยกเว้นคำบุพบท

2. ผู้นิพนธ์ (authors) เขียนชื่อ นามสกุล และคุณวุฒิของผู้นิพนธ์ คุณวุฒิภาษาไทย เขียนด้วยตัวย่อตามพจนานุกรม เช่น พ.บ. ว.ว.ศัลยศาสตร์ หรือ วท.บ. กศ.บ. คุณวุฒิภาษาอังกฤษ ให้เขียนตัวย่อโดยไม่ต้องมีจุด เช่น MD, PhD, FICS, FRCST, MRCOG เป็นต้น หลังคุณวุฒิให้ใส่เครื่องหมายเชิงอรรถ (footnotes) กำกับให้รายละเอียดสถานที่ทำงานในบรรทัดล่างของหน้าแรก เชิงอรรถใช้ตัวเลขเรียงจากเลข 1 ขึ้นไป และให้ใส่เครื่องหมายดอกจันหลังคุณวุฒิของชื่อผู้ติดต่อ หรือ corresponding author และให้ e-mail address ของผู้ติดต่อในบรรทัดล่างสุดของหน้าแรกต่อจากรายละเอียดสถานที่ทำงานของผู้นิพนธ์และผู้นิพนธ์ร่วม

3. บทคัดย่อ (abstract) หมายถึง เรื่องย่อของงานวิจัยซึ่งต้องมีทั้งภาษาไทยและภาษาอังกฤษ เนื้อหาต้องมีความสมบูรณ์ในตัวเอง โดยเขียนให้สั้นที่สุดและได้ใจความ บทคัดย่อทั้งภาษาไทยและภาษาอังกฤษต้องมีเนื้อหาเหมือนกัน ไม่ใส่ตารางหรือแผนภูมิใด ๆ ไม่มีการอ้างอิงเอกสาร ไม่ใส่ตัวเลขหรือข้อความที่ไม่ปรากฏในผลการวิจัย สำหรับบทคัดย่อภาษาอังกฤษให้ใช้ past tense เท่านั้น และให้ใส่ keywords ต่อท้าย ไม่เกิน 3-5 คำหรือวลี เพื่อใช้เป็นดัชนี

นิพนธ์ต้นฉบับให้เขียนบทคัดย่อแบบ structured abstract ส่วนรายงานผู้ป่วยและบทความวิชาการให้เขียนบทคัดย่อแบบปกติย่อหน้าเดียว (standard abstract) ซึ่งควรมีจำนวนคำทั้งหมดไม่เกิน 300 คำ structured abstract ให้เขียน 4 หัวข้อหลัก ซึ่งประกอบด้วย วัตถุประสงค์ (objective) วิธีดำเนินการวิจัย (methods) ผลการวิจัย (results) และสรุป (conclusion) โดยวัตถุประสงค์ควรกล่าวถึงจุดมุ่งหมายหลักที่ต้องการศึกษาหรือทฤษฎีที่ต้องการทดสอบ วิธีดำเนินการวิจัยควรรวมถึงรูปแบบการทำวิจัย สถานที่ทำการวิจัย จำนวนและลักษณะของกลุ่มตัวอย่าง วิธีการรักษาหรือทดลอง ผลการวิจัยหมายถึงผลลัพธ์ส่วนที่สำคัญที่สุดของการศึกษา และสรุปควรเน้นถึงความสำคัญของผลการวิจัย

4. เนื้อหาหลัก ในส่วนของนิพนธ์ต้นฉบับ ควรประกอบด้วย 4 หัวข้อหลัก ได้แก่ บทนำ วิธีดำเนินการวิจัย ผลการวิจัย และวิจารณ์ รายงานผู้ป่วย ควรมี 4 หัวข้อหลัก คือ บทนำ รายงานผู้ป่วย วิจารณ์และสรุป ส่วนบทความวิชาการ ให้ปรับหัวข้อหลักตามความเหมาะสมกับบทความนั้น ๆ

บทนำ ควรกล่าวถึงความเป็นมาของปัญหา เช่น ลักษณะและความสำคัญของปัญหาที่จะนำมาศึกษา มีการเน้นถึงความรู้เดิมของปัญหาโดยอ้างอิงจากเอกสารที่เกี่ยวข้องตามสมควรเพื่อนำผู้อ่านเข้าสู่เรื่องที่จะทำวิจัย รวมทั้งบอกวัตถุประสงค์ในการทำวิจัยอย่างชัดเจน ทั้งนี้บทนำไม่ควรยาวเกินไป ไม่ใส่ข้อมูลผลการวิจัย ตารางหรือแผนภูมิใด ๆ และต้องไม่วิจารณ์หรือสรุปในบทนำ

วิธีดำเนินการวิจัย ควรบอกว่าเป็นรูปแบบการวิจัยชนิดใด กลุ่มตัวอย่างขนาดเท่าใด โดยแสดงวิธีคำนวณขนาดตัวอย่างอย่างสั้น ๆ สุ่มตัวอย่างโดยวิธีใด บอกสถานที่ที่ทำการวิจัย ระยะเวลาที่ศึกษา เกณฑ์การคัดเข้าและเกณฑ์การคัดออก บอกรายละเอียดของการวิจัยว่าดำเนินการอย่างไร เพื่อให้ผู้อื่นสามารถนำไปศึกษาซ้ำได้ หากเป็นวิธีที่ใช้อยู่ทั่วไปอาจบอกเพียงชื่อวิธีการพร้อมเอกสารอ้างอิง แต่ถ้าเป็นวิธีใหม่ ต้องแจงรายละเอียดให้ผู้อ่านเข้าใจ รวมทั้งบอกรายละเอียดของการวิเคราะห์ข้อมูลทางสถิติ ว่าใช้โปรแกรมคอมพิวเตอร์อะไรในการวิเคราะห์ข้อมูล ใช้สถิติอะไรและกำหนดระดับนัยสำคัญเท่าใด

ผลการวิจัย ควรนำเสนอให้เข้าใจง่ายและชัดเจน โดยใช้ตารางและแผนภูมิหรือรูปประกอบ แต่ไม่ใช้ตารางและแผนภูมิในเรื่องเดียวกัน ควรออกแบบให้มีจำนวนตารางและแผนภูมิน้อยที่สุด โดยไม่ควรเกิน 5-7 ตาราง ตารางและแผนภูมิต้องมีเลขที่ และชื่อกำกับ และมีคำอธิบายโดยสรุป เส้นของตารางให้มีเฉพาะเส้นแนวขวาง 3 เส้นที่ด้านบนสุด ด้านล่างสุดของตาราง และเส้นแบ่งหัวข้อตารางกับเนื้อหาเท่านั้น รูปประกอบควรเป็นรูปที่จัดทำขึ้นเอง ถ้าเป็นรูปจากแหล่งอื่นจะต้องระบุที่มา รวมทั้งเอกสารสำเนาลิขสิทธิ์จากสำนักพิมพ์ต้นฉบับด้วย สำหรับรูปผู้ป่วยจะต้องไม่ให้ทราบว่าเป็นบุคคลใดโดยได้รับการปกปิดส่วนที่สามารถระบุถึงบุคคลได้ และอาจจะต้องมีคำยินยอมจากผู้ป่วยด้วย

วิจารณ์ ให้วิจารณ์ผลการวิจัยทั้งหมดที่นำเสนอ สรุปผลการวิจัยสั้น ๆ โดยไม่ต้องลอกข้อความที่เขียนแล้วในผลการวิจัย เปรียบเทียบผลการวิจัยกับการศึกษาอื่น ๆ ให้ความเห็นว่าเหตุใดผลการวิจัยจึงเป็นเช่นนั้น ควรวิจารณ์ข้อจำกัดของการทำวิจัย วิธีดำเนินการวิจัยและความน่าเชื่อถือทางสถิติ รวมทั้งประโยชน์ที่จะนำไปใช้ได้ และการวิจัยที่ควรศึกษาต่อเนื่องต่อไปในอนาคต

5. **Conflict of interest** ให้ระบุว่าผู้นิพนธ์แต่ละท่านมี conflict of interest ใด ๆ หรือไม่ ในจดหมายเพื่อขอพิมพ์

6. **กิตติกรรมประกาศ** แสดงความขอบคุณผู้สนับสนุนการทำวิจัย เช่น ผู้ให้การสนับสนุนทางด้านเทคนิค เครื่องมือที่ใช้ และทางการเงิน นอกจากนี้ควรขอบคุณหน่วยงานหรือผู้รับผิดชอบข้อมูล และผู้ให้คำแนะนำด้านต่าง ๆ

7. **เอกสารอ้างอิง** ให้ใส่หมายเลข 1,2,3 ไว้ท้ายประโยคโดยพิมพ์ตัวยกสูงโดยไม่ต้องใส่วงเล็บ เอกสารที่อ้างอิงเป็นอันดับแรกให้จัดเป็นหมายเลข 1 และเรียงลำดับก่อนหลังต่อ ๆ ไป หากไม่มีความจำเป็นไม่ควรอ้างอิง abstract, unpublished paper, in press หรือ personal communication นิพนธ์ต้นฉบับควรมีเอกสารอ้างอิงไม่เกิน 30 รายการ และไม่ควรใช้เอกสารอ้างอิงที่เก่าเกินไป เอกสารอ้างอิงทั้งหมด รวมทั้งเอกสารอ้างอิงภาษาไทย ให้เขียนเป็นภาษาอังกฤษ โดยเขียนตาม Vancouver guideline ซึ่งกำหนดโดย International Committee of Medical Journal Editors โดยมีหลักโดยย่อดังนี้

ชื่อผู้เขียน ให้ใช้ชื่อสกุลตามด้วย อักษรแรกของชื่อต้นและชื่อกลางเป็นตัวพิมพ์ใหญ่ ใส่ชื่อผู้เขียนทุกคนคั่นด้วยเครื่องหมายจุลภาค ถ้าเกิน 6 คน ใส่ชื่อ 6 คนแรก ตามด้วย et al

การอ้างอิงวารสาร ให้ใส่ชื่อผู้เขียน. ชื่อเรื่อง. ชื่อย่อวารสารตาม index medicus. ปี ค.ศ.; ปีที่ (volume): หน้าแรกถึงหน้าสุดท้าย. โดยเลขหน้าที่ซ้ำกันไม่ต้องเขียน เช่นหน้า 124 ถึงหน้า 128 ให้เขียน 124-8.

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การอ้างอิงหนังสือตำรา ให้เขียน ชื่อผู้เขียน. ชื่อหนังสือ. ครั้งที่พิมพ์ (ถ้าพิมพ์ครั้งแรกไม่ต้องเขียน). ชื่อเมือง (ใช้ชื่อเมืองแรกชื่อเดียว): ชื่อโรงพิมพ์; ค.ศ. p.หน้าแรกถึงหน้าสุดท้าย.

ตัวอย่าง: Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence based medicine: how to practice and teach EBM. 3rd ed. Edinburgh: Churchill Livingstone; 2005. p.10-5.

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ตัวอย่าง: Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. The genetic basis of human cancer. New York: McGraw-Hill; 2002. p.93-113.

การอ้างอิงบทคัดย่อจากที่ประชุมวิชาการ (published proceedings paper)

ตัวอย่าง: Berger H, Klemm M. Clinical signs of gastric ulcers and its relation to incidence [abstract]. In: Chuit P, Kuffer A, Montavon S, editors. 8th Congress on Equine Medicine and Surgery; 2003 Dec 16-18; Geneva, Switzerland. Ithaca (NY): International Veterinary Information Service (IVIS); 2003. p. 45.

การอ้างอิงจากวารสาร/ข้อมูลทางอิเล็กทรอนิกส์:

ตัวอย่าง: International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals [Internet]. 2014 [updated 2014 Dec 1; cited 2015 Jan 30] Available from: http://www.icmje.org/icmje-recommendations.pdf.

การอ้างอิงจากวิทยานิพนธ์

ตัวอย่าง: Liu-Ambrose TY. Studies of fall risk and bone morphology in older women with low bone mass [dissertation]. [Vancouver (BC)]: University of British Columbia; 2004. 290 p.

การแก้ไขบทความเพื่อส่งตีพิมพ์

ให้ผู้นิพนธ์แก้ไขบทความ และอธิบายชี้แจงข้อสงสัยตามที่ผู้กลั่นกรอง และกองบรรณาธิการให้ข้อเสนอแนะให้ครบทุกประเด็น และควรเน้นหรือขีดเส้นใต้ส่วนที่ได้แก้ไขในบทความพร้อมทั้งมีจดหมายสั้น ๆ ระบุว่าได้แก้ในประเด็นใดบ้าง รวมทั้งอธิบายประเด็นที่ไม่ได้แก้ไขให้ผู้นิพนธ์ส่งคืนบทความที่แก้ไขแล้ว พร้อมทั้งบทความเดิมที่ได้รับจากกองบรรณาธิการภายใน 4 สัปดาห์หลังได้รับบทความ ถ้าภายใน 12 สัปดาห์ ผู้นิพนธ์ไม่ส่งบทความคืน หรือไม่ได้แก้ไขบทความตามคำแนะนำ ทางกองบรรณาธิการขอสงวนสิทธิ์ในการถอนบทความออกจากการพิจารณาบทความเพื่อตีพิมพ์

Instructions for Authors

Vajira Medical Journal (Vajira Med J) is the official medical journal of the Faculty of Medicine Vajira Hospital, Navamindradhiraj University. The journal was established in 1957 and, since then, has been regularly published 6 issues per year (January-February, March-April, May-June, July-August, September-October and November-December). The aim is to provide medical knowledge, medical education, and other biomedical sciences information in various types of publications: original article, case report, and review article.

A Key focus of Vajira Med J is on basic and clinical science in urban medicine, including but not limited to epidemiology, etiology, pathogenesis, diagnosis and management for a better health of urban population.

Vajira Med J is a peer reviewed journal with an editorial policy of anonymous (when the reviewers' name are unrevealed) and blind review (when the authors' name are removed from the manuscript submitted for review). All submitted manuscripts are promptly assigned, by the Editor-in- Chief, to two or more members of the editorial board members who are expertise in the field to review the content in terms of ethics, methodology, accuracy, and clarity. In the event that the article is accepted, the corresponding author will receive 30 copies of the paper after it is published.

Submission of a manuscript implies that the article or any part of its essential substance, tables, or figures has not been previously published or not under consideration for publication elsewhere. This restriction does not apply to abstract or published proceedings to the scientific meetings, or an academic thesis. If accepted, it will not be published elsewhere in the same form, in Thai, English or in any other languages, without written consent from the Journal. The Editorial Board reserves the right to modify the final submission for editorial purposes. The intellectual content of the paper is the responsibility of the authors. The Editors and the Publisher accept no responsibility for opinions and statements of the authors.

Preparation of manuscripts

General requirements

All manuscripts can be submitted online (https://tci-thaijo.org/index.php/VMED and http://thailand.digitaljournals.org/index.php/VMJ/) or sent to email: sathit@nmu.ac.th 3 copies in print and on electronic data file via CD, diskette or email along with a cover letter and the checklist guideline. A cover letter must include name and title of the first or corresponding author, full address, telephone number, fax number, and e-mail address, title and category of the submitted manuscript: original article, case report, or review articles. The letter should contain the declared statements that the manuscript has been read and approved by all the authors in terms of the content and accuracy, and that the manuscript has not been previously published or is not under consideration for publication elsewhere. Previous publication in the form of abstract, published proceedings in the scientific meetings, or academic thesis is acceptable for a duplication or modification with an information (or declaration) to the editorial board. If applicable, a copy of ethics approval document should be sent along with the manuscript.

The article must be written in clear and concise Thai, or English. If the manuscript is written in Thai, English is allowed only when Thai word/phrase is unable to make the sentence clear. When English is used, lowercase letters are required. The numbers must be typed in Arabic. The text must be typed double-spaced, in single column, with 1 inch unjustified right margin on A4 paper. Cordial New in 16 pt. size is the preferred font style.

Checklist guideline for an author to submit a manuscript

To facilitate the manuscript preparation and submission, the authors must complete the checklist form and send it along with the manuscript. Any submitted manuscript without checklist form, incomplete data, or incorrect format will be returned to the corresponding author before proceeding. Checklist forms for various types of manuscript can be downloaded from Vajira Med J website (http://www.vajira.ac.th/vmj).

Manuscript Preparation

For researches which fit into any of the following study designs: randomized controlled, diagnostic test or observational studies should follow consort 2010 checklist, STARD checklist and STROBE checklist respectively. These checklists can be downloaded through our website.

The author should prepare the manuscript according to the Uniform Requirements for Manuscript Submitted to Biomedical Journals of the International Committee of Medical Journal Editors. (http://www.icmje.org/recommendations/). Briefly, the manuscripts should be structured in the following order: title and authors, abstract, main text, acknowledgments, and references.

1. **Title:** the title should be concise and suitable for indexing purposes. The first letter of each word should be in capital letter except for a preposition and an article.

2. **Authors:** all contributing author(s) with full name, graduate degree, and department and institutional affiliation of each author are required. E-mail address of the corresponding author should also be addressed.

3. **Abstract:** The abstract must be submitted in duplicate, both in Thai and English. Both Thai and English abstract should have similar or parallel contents. It should be concise and stand for the article. Tables, figures, or references are not included in the abstract as well as the figures or results which do not appear in the article. A standard abstract in one paragraph without subheading is required for case report and review articles and should be limited to 300 words. Below the English abstract list 3-5 keywords for indexing purposes.

A structured abstract is required for original article. It must consist of 4 concise paragraphs under the headings: Objective(s), Methods, Results, and Conclusion(s). The **objective(s)** reflect(s) the purpose of the study, i.e. the hypothesis that is being tested. The **methods** should include the study design, setting of the study, the subjects (number and type), the treatment or intervention. The **results** include the salient outcome(s) of the study. The **conclusion**(s) state(s) the significant results of the study.

4. Main text: The text should be structured with the headings of **introduction, methods, results, and discussion** for original articles, and of **introduction, case report, discussion and conclusion** for case report. Review articles should have heading appropriate for the article.

The **introduction** should state clearly the objective(s) and rationale for the study and cite only the most pertinent references as background. The **methods** should include study design, subjects with inclusion and exclusion criteria, material, methods and procedures utilized with enough details for the study to be repeated, sample size calculation, and the statistical software and methods employed. The **results** should describe the study sample and data analyses to answer the objectives. There should be no more than 5-7 figures and tables (total) per manuscript. For the table, only horizontal lines above and below the heading and at the bottom of the table are made without any column line. The figures used should be original, any modification from other sources should be clearly indicated and state the site of the origin with written permission. If any photographs of the patients are used, they should not be identifiable or the photographs should be accompanied by written permission to use them. The **discussion** should briefly summarize or emphasize the main findings, interpret or explain their findings in comparison with other reports, state any limitation of the study, describe an impact on healthcare if any, and comment on the potential for future research.

5. Conflict of interest: the authors should declare the conflict of interest in the cover letter.

6. Acknowledgments: the authors should include only those who have made a valuable contribution to the work presented but who do not qualify as authors. This may include an involved patient population and any grant support.

7. References: state the references consecutively in the order in which they are first mentioned in the text. Use arabic numerals in superscription without parenthesis for reference in the text. Unpublished data and personal communications is not allowed. Published abstracts can be used as numbers references; however, reference to the complete published article is preferred. The references should be upto- date in that subject and be no more than 30 references for original articles. The 'Vancouver style' of references must be applied. List all authors when there are 6 or fewer, and list the first 6 and add 'et al' when there are 7 or more authors. Please refer to further detail of the reference format in the NEJM or official website of our journal.

Examples:

Journals

Tangjitgamol S, Hanprasertpong J, Manusirivithaya S, Wootipoom V, Thavaramara T, Buhachat R. Malignant ovarian germ cell tumors: clinico-pathological presentation and survival outcomes. Acta Obstet Gynecol Scand. 2010; 89: 182-9.

Books

Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence based medicine: how to practice and teach EBM. 3rd ed. Edinburgh: Churchill Livingstone; 2005. p.10-5.

Chapter in Books

Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. The genetic basis of human cancer. New York: McGraw-Hill; 2002. p.93-113.

Published proceedings paper

Berger H, Klemm M. Clinical signs of gastric ulcers and its relation to incidence [abstract]. In: Chuit P, Kuffer A, Montavon S, editors. 8th Congress on Equine Medicine and Surgery; 2003 Dec 16-18; Geneva, Switzerland. Ithaca (NY): International Veterinary Information Service (IVIS); 2003. p. 45.

Electronic journals/data

International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals [Internet]. 2014 [updated 2014 Dec 1; cited 2015 Jan 30] Available from: http://www.icmje.org/icmje-recommendations.pdf.

Thesis

Liu-Ambrose TY. Studies of fall risk and bone morphology in older women with low bone mass [dissertation]. [Vancouver (BC)]: University of British Columbia; 2004. 290 p.

Manuscript revision

All comments or queries returned to the authors for a revision or clarification should be thoroughly addressed or revised accordingly. The revised manuscript must be underlined or highlighted for the changes, and re-submitted, preferably, within four weeks to prevent a delay of a final decision. A maximum of 12 weeks is allowed for a revision or the editorial board will take the right to withdraw the manuscript from the submission system. The original manuscript must be returned along with the printed and electronic revised version. An accompanying summarized letter of revision point by point may expedite the re-review.

วชิรเวชสาร
และวารสารเวชศาสตร์เขตเมือง
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สารบัญ

หน้า

วชิรเวชสาร
และวารสารเวชศาสตร์เขตเมือง
Vajira Medical Journal:
Journal of Urban Medicine

ปีที่ 66 ฉบับที่ 2 มีนาคม - เมษายน พ.ศ. 2565 Vol. 66 No. 2 March - April 2022

สารบัญ

หน้า

Clinical Characteristics and Outcomes of Acute Myeloid Leukemia in Vajira Hospital-a 9-year Single Center Retrospective Study

Dusit Jit-ueakul MD[1*]

[1] Division of Hematology, Department of Medicine, Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand

* Corresponding author, e-mail address: dusit.j@nmu.ac.th

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Abstract

Objective: To collect demographic data, management patterns and outcomes of acute myeloid leukemia (AML) patients in a tertiary hospital.

Methods: We collected data of newly diagnosed AML patients from 2008 to 2016, including clinical presentation and characteristics at the time of diagnosis. Survivals and factors affecting outcomes were evaluated.

Results: There were 106 patients enrolled in the study. More than half of the patients were in the younger age group, which had a median age 56.5 years (41.5-73.5). Initial symptoms at presentation were anemia, fever and bleeding tendency. The younger age group had a good performance status presented by Eastern Cooperative Oncology Group (ECOG) score of less than two. Intensive chemotherapy was utilized in treatment of most patients in the younger group (85.7%) as compared with the elderly group (18%). Better intensive chemotherapy significantly improved median survival (256 vs 79 days; $p < 0.001$).

Conclusion: AML patients who had received intensive chemotherapy had a survival advantage irrespective of age.

Keywords: acute myeloid leukemia, chemotherapy, performance status, survival

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ลักษณะทางคลินิกและผลการรักษาของโรคมะเร็งเม็ดเลือดขาวเฉียบพลันชนิดมัยอีลอยด์ การศึกษาแบบย้อนหลัง 9 ปี ในโรงพยาบาลวชิรพยาบาล

ดุสิต จิตรเอื้อกุล พ.บ.[1*]

[1] สาขาโลหิตวิทยา ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย

* ผู้ติดต่อ, อีเมล: dusit.j@nmu.ac.th

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บทคัดย่อ

วัตถุประสงค์: การศึกษาจากข้อมูลย้อนหลัง 9 ปีเกี่ยวกับข้อมูลพื้นฐาน การรักษาและผลการรักษาในโรคมะเร็งเม็ดเลือดขาวเฉียบพลันชนิดมัยอีลอยด์ในคณะแพทยศาสตร์วชิรพยาบาล

วิธีดำเนินการวิจัย: การศึกษานี้เก็บข้อมูลตั้งแต่ปีค.ศ. 2008 ถึง 2016 เกี่ยวกับอาการแสดง และลักษณะทางคลินิกเมื่อวินิจฉัย มีการประเมินการรอดชีพและปัจจัยที่ส่งผลต่อการรอดชีพ

ผลการวิจัย: ผู้ป่วยทั้งหมด 106 คนในการศึกษานี้ มากกว่าครึ่งของผู้ป่วยเป็นกลุ่มอายุน้อยกว่า ค่ามัธยฐานอายุอยู่ที่ 56.5 ปี (ระหว่าง 41.5 - 73.50) อาการแสดงนำได้แก่ ภาวะซีด ไข้ และภาวะเลือดออก กลุ่มอายุน้อยมักจะมีสมรรถนะร่างกายดีที่คะแนน Eastern Cooperative Oncology Group (ECOG) น้อยกว่า 2 ผู้ป่วยกลุ่มอายุน้อยได้รับยาเคมีบำบัดขนาดสูงที่ร้อยละ 85.7 เปรียบเทียบกับกลุ่มผู้ป่วยสูงอายุที่ร้อยละ 18 การได้รับยาเคมีบำบัดขนาดสูงเป็นปัจจัยเดียวที่เพิ่มอัตราการรอดชีพอย่างมีนัยสำคัญ (256 ต่อ 79 วัน; $p < 0.001$).

สรุป: ผู้ป่วยโรคมะเร็งเม็ดเลือดขาวเฉียบพลันชนิดมัยอีลอยด์ที่ได้รับยาเคมีบำบัดขนาดสูงเพิ่มอัตราการรอดชีพได้โดยไม่ขึ้นกับอายุ

คำสำคัญ: โรคมะเร็งเม็ดเลือดขาวเฉียบพลันชนิดมัยอีลอยด์, ยาเคมีบำบัด, สมรรถนะร่างกาย, การรอดชีพ

วันที่รับบทความ 23 กุมภาพันธ์ 2564 **วันแก้ไขบทความ** 19 กุมภาพันธ์ 2565 **วันตอบรับบทความ** 6 เมษายน 2565

Introduction

Acute myeloid leukemia (AML) is the most common leukemia among adults and can occur within all age groups, particularly increasing with advanced age[1]. AML is the heterogeneous disease in terms of etiology, risk factors, and genetic predispositions. Prognosis of disease depends on many factors[2]. The clinical manifestation of bone marrow failure is the indication to diagnose AML. Nowadays, survival has been improved dramatically due to more intensive strategies including, intensive chemotherapy, molecular-targeted therapies, stem cell transplantation and supportive cares. However, AML still has poorer prognosis when compared to other hematologic malignancies[3]. A single center study had previously reported the 5-year overall survival (OS) of only 22.2%[4]. Notably, the OS declined among elderly patients aged more than 60 years according to a recent study from Thai Acute Leukemia Working Group (TALWG)[5]. Clinical factors associated with better survival were younger age (Age < 60 years), good ECOG PS and less comorbidities[6]. Since the 1970's, the intensive "7+3 regimen" had been the standard of care which resulted in 30 – 40% chance of long-term remission among the younger age group[7]. The proportion of patients who were eligible for intensive induction chemotherapy depends on age and performance status. The aim of this study was to describe the patients' demographics, clinical characteristics at the time of AML diagnosis and management between age groups. Treatment responses and survival outcome were determined, and clinical factors associated with survival were evaluated.

Methods

This study was a nine-year retrospective cohort study conducted in the Division of Hematology, Department of Medicine, Faculty of Medicine, Vajira Hospital, Navamindradhiraj University. Patients who were newly diagnosed from January 1, 2008, to December 31, 2016 were included. The inclusion criterion was age ≥ 15 years old at time of diagnosis according to the 2008 revision of the World Health Organization (WHO) classification of myeloid neoplasms and acute leukemia[8-9]. Those with acute lymphoblastic leukemia (ALL), mixed phenotype acute leukemia, myelodysplastic syndrome (MDS), myeloproliferative neoplasms (MPN), relapsed disease, chronic myeloid leukemia (CML) with blastic phase and patients with unretrievable medical records were also excluded. The primary objective was to determine treatment response. Survival analysis and factors associated with better survival were the secondary objectives.

Terminology

The patients were categorized into two age groups. The ***younger age group*** included patients less than 60 yeas old. Those who aged equal to or greater than 60 years were defined as ***the elderly group***. The performance status was determined according to ECOG cancer research group. Anemia, fever and bleeding were documented as reported in the medical records. Cytogenetic results were classified according to WHO 2008 classification[8]. According to the definition defined in 2017 European LeukemiaNet (ELN) recommendation on the clinical outcomes: complete remission (CR) was determined when bone marrow blast < 5%, absence of circulating blasts and blasts with Auer's rod, absence of extramedullary blast, transfusion free, absolute neutrophil count > 1 x 10^9/L (> 1,000/μL) and platelet > 100 x 10^9/L (> 100,000/μL)[10].

Statistical Analyses

According to the data reported by frequency and percentage for categorical variables. Continuous variables were expressed as mean and SD or median and interquartile range if normality criteria. The continuous variables were compared between both age groups using Mann-Whitney *U* test and Student *t* test, as appropriate. The categorical variables were compared between both age groups using Fisher's exact test or Chi-square test, as appropriated. Overall survival between both age groups was estimated using Kaplan-Meier method

and compared by using log-rank test. Factors associated with survival were determined using Cox proportional hazards models. Hazard ration (HR) and 95% confidence interval across subgroups were reported, and *p*-value < 0.05 was determined as statistical significance. The data analyses were performed by STATA, version 13 (StataCorp, College Station, Texas, USA, 2013).

Result

There were 129 patients recruited in the nine-year period of this study, 23 patients were excluded according to the exclusion criteria. There were 106 AML patients were eligible for data analyses. There were 56 patients (52.8%) in the ***younger group*** and 50 patients (47.2%) in the ***elderly group*** (Figure 1). The median age was 56.5 years (IQR: 41.5 - 73.50). Half of them were male. Most of the participants were categorized into AML (69.8%). The rest of the patients were 21.7% AML with myelodysplastic-related change (AML-MRC) and 8.5% acute promyelocytic leukemia (APL). Leading clinical presentations at diagnosis were anemia (64.2%) and fever (60.4%), followed

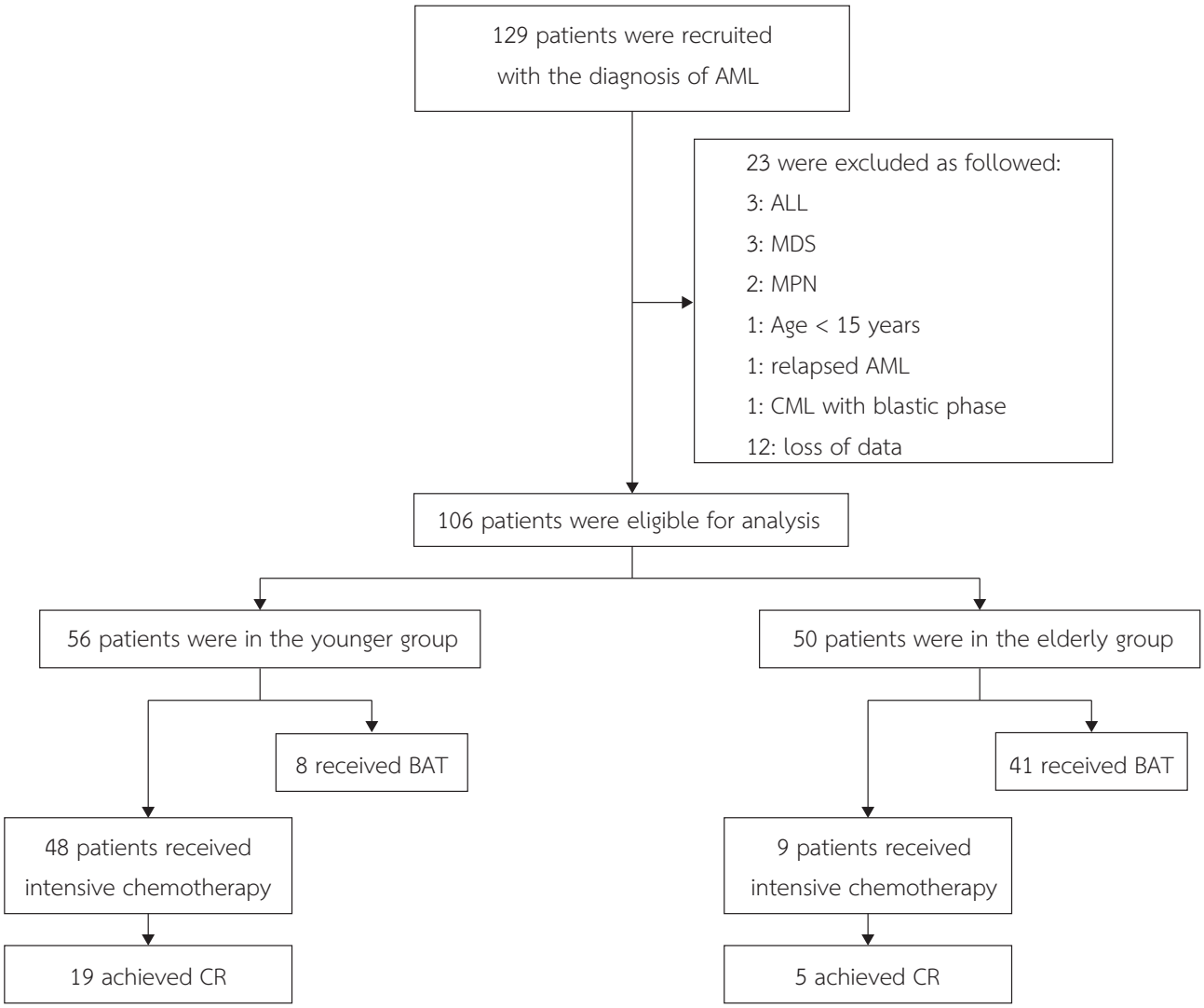

Figure 1: Patients recruitment in the study, treatment management and response. ALL: acute lymphoblastic leukemia; AML: acute myeloid leukemia; BAT: best available therapy; CML: chronic myeloid leukemia; CR: complete response; MDS: myelodysplastic syndrome; MPN: myeloproliferative neoplasms.

with bleeding (26.4%). More than half of the patients (51.9%) were in good performance status (ECOG 0 – 1). The initial blood counts at diagnosis were a mean hemoglobin of 8.6 g/dl (6.9 – 9.4), a median platelet count of 41 x 10^9/l (20.75-79.00), and a median white blood cell count of 17.35 x 10^9/l (4.8-68.9). A median peripheral and bone marrow myeloblast counts were 42.5% (13 – 69) and 50.6% (37 – 76), respectively. Most of the patients, especially those who were diagnosed in earlier years lacked the cytogenetic data. The cytogenetics results were available in 32 patients (30.2%). Normal karyotype was the most frequent result (12.3%) in this study. (Table 1)

Clinical presentation between younger and elderly group

The young age group had statistically significant better performance status (as defined as ECOG PS 0 – 1) compared with the elderly (82.1% vs 18.0%); $p < 0.001$). The younger age group had a greater percentage of fever (69.6% vs 50.0%; $p < 0.04$) and had higher hemoglobin level than the elderly group (9.0 g/dl vs 7.2 g/dl, $p < 0.001$). However, the bone marrow myeloblast cell counts were not different between both groups (50.6% vs 57.4%, $p = 0.86$). (Table 1)

Table 1:
Clinical characteristics and outcomes in the whole cohort, younger and older age groups of patients with AML

Characteristics	Total (n=106) (%)	AML in younger age group (n=56) (%)	AML in elderly age group (n=50) (%)	p-value
Age (year), Median (IQR)	56.5 (41.5-73.5)	44 (33-50)	73.5 (66-78)	
Male	52 (49.1)	30 (53.6)	22 (44.0)	0.33
Diagnosis				
Acute myeloid leukemia (n=74)	74 (69.8)	41 (73.2)	33 (66.0)	0.07
Acute promyelocytic leukemia	9 (8.5)	7 (12.5)	2 (4.0)	
AML with MDS-related change	23 (21.7)	8 (14.3)	15 (30.0)	
Clinical manifestation				
Anemia	68 (64.2)	31 (55.4)	37 (74.0)	0.05
Fever	64 (60.4)	39 (69.6)	25 (50.0)	0.04
Bleeding	28 (26.4)	17 (30.4)	11 (22.0)	0.33
Previous malignancy	5 (4.7)	1 (1.8)	4 (8.0)	0.19
Associated myeloid sarcoma				
Yes	5 (4.7)	2 (3.6)	3 (6.0)	0.67
ECOG				
0 – 1	55 (51.9)	46 (82.1)	9 (18.0)	<0.001
2 – 4	37 (34.9)	5 (8.9)	32 (64.0)	
NA	14 (13.2)	5 (8.9)	9 (18.0)	

Table 1:

Clinical characteristics and outcomes in the whole cohort, younger and older age groups of patients with AML (Continued)

Characteristics	Total (n=106) (%)	AML in younger age group (n=56) (%)	AML in elderly age group (n=50) (%)	p-value
Complete Blood Count				
Median Hb (IQR) (g/dl)	8.6 (6.9-9.4)	9 (7.9-10.3)	7.2 (5.6-8.9)	<0.001
Platelets (x 10^9/l)	41 (21-79)	38 (20-72)	49 (22-85)	0.41
WBC (x 10^9/l)	17.4 (4.8-69)	16.9 (5.1-66.6)	22.9 (3.5-70.2)	0.81
Myeloblast (%)	42.5 (13-69)	47.5 (17-69)	32 (11-74)	0.29
Bone marrow myeloblast (%)	51 (37-76)	51 (39-79)	57 (23-79)	0.86
Cytogenetics				
Normal cytogenetics	13 (12.3)	8 (14.3)	5 (10.0)	0.21
t(15;17)	6 (5.7)	4 (7.1)	2 (4.0)	
t(8;21)	1 (0.9)	1 (1.8)	0 (0.0)	
inv(16) or t(16;16)	3 (2.8)	3 (5.4)	0 (0.0)	
t(v;11q23) MLL rearranged	1 (0.9)	0 (0.0)	1 (2.0)	
Others	8 (7.5)	2 (3.6)	6 (12.0)	
Treatment				
Intensive chemotherapy	57 (53.8)	48 (85.7)	9 (18.0)	<0.001
Response				
Complete Response (CR) achieved	24 (22.6)	19 (33.9)	5 (10.0)	0.003

AML: acute myeloid leukemia, BM: bone marrow, ECOG: Eastern Cooperative Oncology Group, Hb: hemoglobin, IQR: Interquartile range, MDS: myelodysplastic, WBC: white blood cell.

Treatment and outcomes between the younger and elderly group

The standard of care for patients with AML were "7 + 3 regimen" (cytarabine 100 – 200 mg/m^2/day for 7 days, and idarubicin 12 mg/m^2/day for 3) and followed by 3 – 4 cycles of consolidation therapy with high dose cytarabine (3,000 mg/m^2 every 12 hours on day 1, 3, and 5) for patients who achieved complete remission after induction. All-trans retinoic acid (ATRA) and idarubicin were the induction protocol for APL. Hydroxyurea, a less intense chemotherapy regimen, and transfusion support were the best available therapy provided for non-fit or frail patients. Most patients (88.5%) in the younger age group were treated with intensive chemotherapy as compared to only 18% in elderly group. As expected, complete response was achieved more frequently in the younger group than in the elderly group (33.9% vs 10.0%; p = 0.003). Overall CR was achieved in 42.1% in all patients who had received induction chemotherapy.

The median follow-up of this cohort was 4.2 months. The median survival in the younger group was 6 months, compared to 3.6 months in the elderly group (Figure 2) which did not achieve a statistical significance (p = 0.062). Nine patients

with APL had excellent outcomes, which the median survival was not reached at the time of analysis and 55.6% of patients survived beyond 3 years. (Table 2)

In the univariate analysis, age group did not have an impact on either progression-free survival (PFS) or overall survival (OS). The mortality was significantly higher in the poor performance status group (HR = 2.49; 95%CI 1.58 – 3.93; $p < 0.001$), and intensive treatment decreased the mortality of disease (HR = 0.39; 95%CI 0.25 – 0.59; $p < 0.001$). A condition of hypoalbuminemia was a trend of negative impact to our survival (HR = 1.52; 95%CI 0.99 – 2.26; $p = 0.053$).

In the multivariate analysis, only intensive chemotherapy had positive impact on overall survival (HR = 0.39; 95%CI 0.19 – 0.81; $p = 0.01$). (Table 3) After multivariate analyses, patients who had received intensive chemotherapy significantly improved median survival (256 vs 79 days; $p < 0.001$). Moreover, one-fourth (15 in 56) of patients receiving intensive chemotherapy survived after 2-year follow up. (Figure 3) Interestingly, we found that more than more than half (55%) of elderly patients who had received chemotherapy achieved complete response.

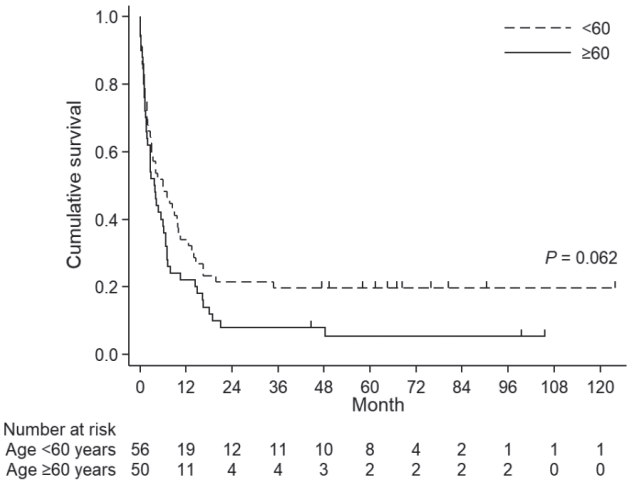

Figure 2: Cumulative survival between younger and older age groups of patients with AML.

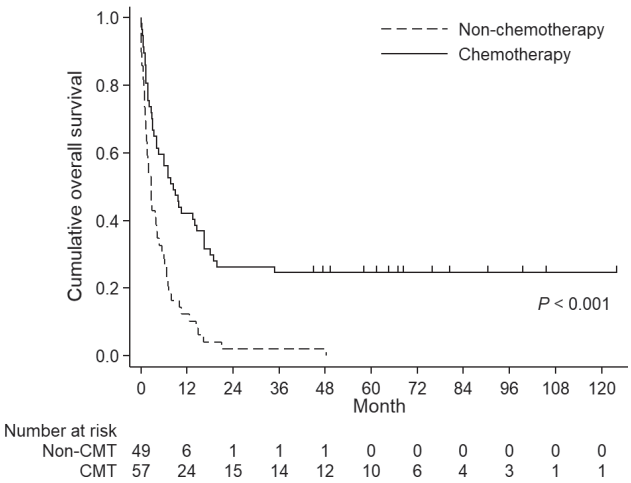

Figure 3: Cumulative survival between intensive chemotherapy and non-chemotherapy group. CMT (chemotherapy)

Table 2:

Univariate analysis of overall survival in different subtypes of AML

Variables	2-yr OS (%)		3-yr OS (%)		p-value
	Rate	(95% CI)	Rate	(95% CI)	
Acute myeloid leukemia	13.5	(6.9-22.3)	12.2	(6.0-20.7)	0.019
Acute promyelocytic leukemia	55.6	(20.4-80.5)	55.6	(20.4-80.5)	
AML with MDS-related change	4.4	(0.3-18.2)	4.4	(0.3-18.2)	

MDS: myelodysplastic

Table 3:

Univariate and multivariate analysis for mortality of patients with AML (n=106)

Factors	Mortality Outcome					
	Univariate analysis			Multivariate analysis		
	HR	95%CI	p-value	HR_{adj}	95%CI	p-value
Age (year)						
<60	1.00	Reference				
≥60	1.47	(0.98-2.23)	0.06			
ECOG						
<2	1.00	Reference		1.00	Reference	
≥2	2.49	(1.58-3.93)	<0.001	1.76	(0.87-3.54)	0.12
Intensive Chemotherapy						
No	1.00	Reference		1.00	Reference	
Yes	0.39	(0.25-0.59)	<0.001	0.39	(0.19-0.81)	0.01
Albumin at diagnosis (g/dl)						
>3.5	1.00	Reference				
<3.5	1.50	(0.99-2.26)	0.053			

ECOG: Eastern Cooperative Oncology Group score

Discussion

Our study emphasized in clinical presentation, utilization of intensive chemotherapy and survival of AML patients in a real setting. Median age of AML patients diagnosed in this study was 56.5 years. Elderly patients accounted for 47%, their median age was 73.5 which was similar to Thai Acute Leukemia Study Group Registry in 2018[5] and Swedish registry at 71 years[11]. The proportion of the elderly AML was also similar to the Löwenberg's review in 2001[12]. The prevalence of AML-MRC was 21.7%, as compared to 7.2% in the reported by Kulsoom, et al., which may be due to a higher proportion of elderly patients in our study[13]. The current study also demonstrated the unmet need in older AML patients. Only a minority of the elderly patients (18.1%) who were aged between 60 – 67 years received intensive chemotherapy. However the CR rate of older patients who received intensive chemotherapy were 55.6% (5 out of 9 patients) which was greater than CR rate reported in the study from Brazil [14] but similar to the study report by Almeida AM. and Ramos F[15] The higher rate of CR in older patients in the current study was likely due to the higher proportion of APL in the older age group which the intensive inductions were more likely to be given. (Figure 4) The current study also confirmed that patients who received intensive induction chemotherapy has better survival that supportive care, even in the elderly patients. There data supported the survival benefit in elderly patients with AML in good performance who could tolerate intensive chemotherapy[5].

Despite the fact that older patients with AML are in vulnerable state, many studies have demonstrated the benefit of intensive induction chemotherapy when offered to a relatively younger subset of patients. Other factors which effect survival and proper delineation of frailty and comorbidities should be explored in future research to select appropriate patients for induction chemotherapy which could result in better outcomes.

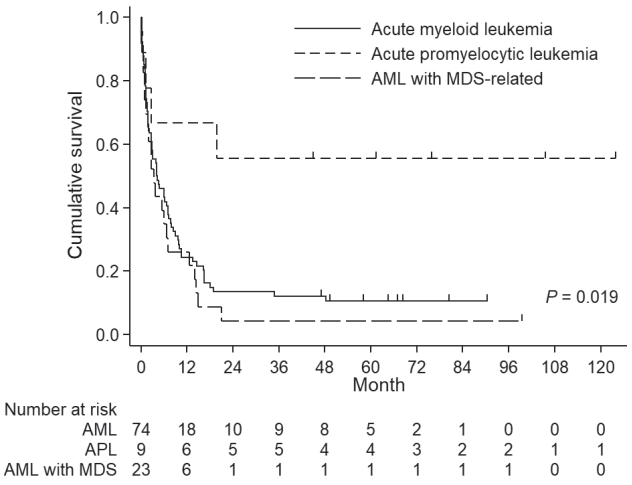

Figure 4: Survival and AML with specific subtypes. APL: acute promyelocytic leukemia, AML: acute myeloid leukemia, MDS: myelodysplasia

There are several limitations in this study. Firstly, the cytogenetics results which are surrogate marker for prognosis and risk stratification was not available in the majority of patients. The WHO classification of Tumours and Haematopoietic and Lymphoid Tissues had proposed a cytogenetic-based classification in 2008, however the official publication came out later and there was a lag in the implement of the treatment policy. Therefore, prognostic prediction and risk stratification according to genetic basis was not available in the current study. Secondly, due to limited sample size, the heterogeneity between the two age groups cannot be compared. The nationwide registration study with larger numbers of patients would offer better information than the current study.

Conclusions

Treatment with intensive chemotherapy had a significant impact on survival in AML. Good ECOG performance status reflects functionality and may predict tolerability for the treatment even in the elderly AML patients. Intensive chemotherapy significantly improves the survival irrespective of age.

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Disclosure

None

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Treatment Outcomes after Breast Conserving Therapy in Breast Cancer Patients in Faculty of Medicine, Vajira Hospital: a 10-Year Retrospective Study

Kanisa Rongsriyam MD[1]
Kamonrat Sueangamiam MSc[2*]
Thanatip Tantivatana MD[1]

[1] Department of Radiology, Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand
[2] Department of Radiological Technology, Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand
* Corresponding author, e-mail address: kamonrat@nmu.ac.th
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Abstract

Objective: To study the 5 and 10-year survival rate and prognosis factors in breast cancer patients receiving breast conservative treatment (BCT).

Methods: A retrospective descriptive analysis of BCT patients who were treated in Radiation Oncology unit, Department of Radiology, Faculty of Medicine Vajira Hospital between 2009 and 2019. The Kaplan-Meier method was used for survival analysis. The authors analyzed association of patients and tumor characteristics with survival using the log-rank test and Cox models.

Results: A total of 158 BCT patients were included. Five-year overall and disease-free survivals were 100% and 97.8%, respectively, with 10-year overall survival and disease-free survival were 100% and 95.7%, respectively. Numbers of positive nodes more than 4 (HR of 10.25; 95% CI:1.66-63.18) are significantly prognostic factors related to recurrence.

Conclusions: Breast cancer patients who were treated with BCT had a favorable long-term survival outcome. Survival rates did not change much between 5 and 10 years. The important prognostic factor affecting disease-free survival was axillary lymph node metastasis.

Keywords: breast cancer, BCT, long-term out come

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ผลการรักษาของผู้ป่วยมะเร็งเต้านมที่ได้รับการรักษาแบบสงวนเต้านม ในคณะแพทยศาสตร์วชิรพยาบาล: การศึกษาย้อนหลัง 10 ปี

คณิศา รองศรีแย้ม พ.บ.[1]
กมลรัตน์ เสืองามเอี่ยม วท.ม[2*]
ธนาทิพย์ ตันติวัตนะ พ.บ.[1]

[1] ภาควิชารังสีวิทยา คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย
[2] ภาควิชารังสีเทคนิค คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย
* ผู้ติดต่อ, อีเมล: kamonrat@nmu.ac.th
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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาอัตราการปลอดโรค และอัตราการรอดชีวิต ที่ 5 ปี และ 10 ปี รวมถึงปัจจัยที่มีผลต่อการพยากรณ์โรคในผู้ป่วยมะเร็งเต้านมที่ได้รับการรักษาแบบสงวนเต้านมที่คณะแพทยศาสตร์วชิรพยาบาล

วิธีดำเนินการวิจัย: ทำการศึกษาย้อนหลังในผู้ป่วยมะเร็งเต้านมที่ได้รับการรักษาแบบสงวนเต้านมที่คณะแพทยศาสตร์วชิรพยาบาล โดยเก็บข้อมูลในผู้ป่วยที่รักษาครบตั้งแต่ปี 2552 ถึง 2562

ผลการวิจัย: ผู้ป่วยมะเร็งเต้านมที่รักษาด้วยการสงวนเต้านมทั้งหมด 158 คน อัตราการรอดชีวิต และอัตราการปลอดโรค ที่ 5 ปี เท่ากับร้อยละ 100 และ 97.8 ตามลำดับ อัตราการรอดชีวิต และอัตราการปลอดโรค ที่ 10 ปี เท่ากับร้อยละ 100 และ 95.7 การแพร่กระจายของโรคมะเร็งไปที่ต่อมน้ำเหลืองมากกว่า 4 ต่อม นับว่าเป็นปัจจัยสำคัญในการพยากรณ์โรคที่สำคัญต่ออัตราการปลอดโรค (HR = 10.25; 95% CI:1.66-63.18)

สรุป: ผู้ป่วยมะเร็งเต้านมที่ได้รับการรักษาแบบสงวนเต้านม อัตราการรอดชีวิตค่อนข้างคงที่ระหว่าง 5 ถึง 10 ปี ปัจจัยพยากรณ์โรคสำคัญที่มีผลต่ออัตราการปลอดโรคคือ การแพร่กระจายของโรคมะเร็งมาที่ต่อมน้ำเหลือง

คำสำคัญ: มะเร็งเต้านม, การรักษาแบบสงวนเต้านม, ผลการรักษาระยะยาว

วันที่รับบทความ 16 กรกฎาคม 2564 **วันแก้ไขบทความ** 15 ตุลาคม 2564 **วันตอบรับบทความ** 7 เมษายน 2565

Introduction

Breast cancer is the most commonly diagnosed cancer and the leading cause of cancer-related deaths in women worldwide including Thailand, with global trends indicating rising rates of incidence and mortality[1-3]. Breast cancer treatment is multidisciplinary. The treatment of breast cancer includes the treatment of local disease with surgery, radiation therapy, or both, and systemic treatment with chemotherapy, endocrine therapy, biologic therapy, or combinations of these. The need for and selection of various local or systemic therapies are based on several prognostic and predictive factors. These factors include tumor histology, clinical and pathologic characteristics of the primary tumor, ALN status, tumor ER/PR content, tumor HER2 status, multi-gene testing, presence or absence of detectable metastatic disease, patient co-morbid conditions, patient age, and menopausal status[4-7].

Multiple randomized trials with follow-up of up to 20 years have demonstrated that breast-conserving therapy (BCT) is equivalent to mastectomy in on overall survival and recurrence rate as primary breast local treatment in stage I and II breast cancer women[8-13].

BCT consists of breast-conserving surgery (BCS) plus radiation therapy in the breast area. BCS refers to an operation that aims to remove all cancer while avoiding a mastectomy. Other terms for this operation include lumpectomy, wide local excision, segmental resection, tylectomy, and quadrantectomy. BCT has been increasingly accepted as an alternative to mastectomy in specific patients, as it provides tumor removal while maintaining an acceptable cosmetic outcome, fewer complications, and a better quality of life.

We aimed to evaluate the long-term treatment outcomes and associate factors with the prognosis of breast cancer patients receiving BCT at the Faculty of Medicine, Vajira Hospital.

Methods

The study was approved by the Ethics Committees of the institution (COA O84/2561). Patients diagnosed with pathologically proven breast cancer and were treated with BCT between 2009 and 2019 in the Department of Radiology Faculty of Medicine, Vajira Hospital were retrospectively evaluated. Inclusion criteria were patients who had treated with BCT and completed all treatment. Patients were excluded if they had a history of other cancer or an underlying disease that affects survival, or a history of previous irradiation to the thorax or, a piece of insufficient information. The characteristics features of the patient, tumor, and details of treatment were collected from the patient's medical record.

All patients were treated with BCS, which consists of breast-conserving surgery (BCS) plus radiation therapy in the breast area. After BCS, base on staging, grading, margin, receptor status, and age, high-risk patients who had an indication for systemic therapy went to received adjuvant systemic treatment. The chemotherapy regimen, adjuvant hormonal therapy, and the use of targeted therapy were delivered at the discretion of the oncologist involved in each case. We staged all patients by the 2010 TNM classification system (AJCC 7)[14].

For radiation therapy, the entire breast was treated to a total dose of 50-50.4 Gray (Gy) in 5-6 weeks with medial and lateral tangential fields. Patients were treated once a day, 5 days a week with a daily fraction size of 1.8–2 Gy. The breast tissue extent and treatment coverage of breast tissue were determined clinically. Wedges were the only form of compensation used. An axillary field was added if there were four or more nodes positive. Boost dose was delivered in this select group of women, a total dose 10-15 Gy in 5-7 fractions. The authors also reviewed the duration of delivered radiotherapy after surgery.

All patients were followed up to receive a physical examination every 3 months during the first 2 years then every 6 months until death. The primary outcomes was set as 5-year and 10-year overall survival (OS). The secondary outcomes was set as 5-year and 10-year disease-

free survival (DFS), prognostic factors for survival. OS was obtained from the first day of treatment to the date of death from all causes or last follow-up. DFS was calculated from the first day of treatment until the date of disease progression, recurrence, or right-censored at the time of the last follow-up.

Statistical analysis was performed with SPSS statistical analysis for Windows version 22.0 (IBM Corp, Armonk, NY). DFS and OS were analyzed by the Kaplan Meier method and were compared between groups with the log-rank test. A value of $p<0.05$ was considered statistically significant. Multivariate analysis was performed using Cox proportional hazards regression analysis in a foreword stepwise manner with a p-value of 0.05 as inclusion.

Results

A total of 158 patients were included in the study. The median follow-up times were 6.03 years (range, 1.3 to 16.86 years). The patient characteristics are shown in Table 1. The median age at diagnosis was 47 years (range, 25 to 86 years). The majority of patients (60.8%) were older than 45 years. In 64.6% of the cases, the primary surgical treatment was wide excision and 51.3% had axillary node clearance for lymph node clearance. Negative margins were achieved by surgery in 88.6% of cases, with the remainder of margins positive (8.2%) or unknown (3.2%). Stage I, II, and III were found in the following frequency: 51.3%, 41.1% and 7.6% respectively. Tumor size was smaller than or equal to 5 cm in 96.9% (n = 153). Invasive ductal carcinoma (IDC) was most commonly found, 93% (n = 147) with invasive lobular carcinoma (ILC) only 3.8% (n = 6). Sixty-seven percent of patients had well or moderately differentiated tumors. The detailed histologic evaluation identified the presence of 20.3% of lymphatic or vascular invasion, 67.1% of positive estrogen receptor (ER), 62% of positive progesterone receptor (PR), 20.9% of positive human epidermal growth factor receptor 2 (HER-2) and 25.9% of ≥ 14% proliferative index of Ki-67. Mean and median total radiation dose (initial dose plus boost dose to tumor bed) were 61.45 Gy and 65 Gy (range, 47-66 Gy). Eighty-nine percent of cases had a boost dose, usually with electrons (3/4). Regional lymph node irradiation was performed for 52 patients (32.9%). Chemotherapy was given to 74.1% of patients, most commonly adriamycin/cyclophosphamide. Seventy-five percent of all patients received endocrine therapy and four percent of all patients received targeted therapy.

Table 1:
Patient, tumor and treatment characteristics

Characteristics	n (%)
Age (years)	47 (25-86)
Age group	
< 45	62 (39.2)
≥ 45	96 (60.8)
LN dissection type	
Axillary node clearance	81 (51.3)
Sentinel node procedure	77 (48.7)
Margin status	
Negative	140 (88.6)
Positive	13 (8.2)
Unknow	5 (3.2)
Histologic type	
Ductal	147 (93)
Lobular	6 (3.8)
Others	5 (3.2)
Tumor grade	
Grade I	27 (17.1)
Grade II	78 (49.4)
Grade III	50 (31.6)
Unknow	3 (1.9)
Lymphovascular invasion	
Not present	110 (69.6)
Present	32 (20.3)
Unknow	16 (10.1)

Table 1:
Patient, tumor and treatment characteristics (Continued)

Characteristics	n (%)
ER status	
Negative	43 (27.2)
Positive	106 (67.1)
Unknow	9 (5.7)
PR status	
Negative	48 (30.4)
Positive	98 (62.0)
Unknow	12 (7.6)
Her-2 status	
Negative	93 (58.9)
Positive	33 (20.9)
Unknow	32 (20.2)
Ki67 Index	
< 14 % proliferation index	36 (22.8)
≥ 14 % proliferation index	41 (25.9)
Unknow	81 (51.3)
T stage	
T1	87 (55.1)
T2	66 (41.8)
T3	4 (2.5)
T4	1 (0.6)
N stage	
N0	121 (76.6)
N1	25 (15.8)
N2	10 (6.3)
N3	2 (1.3)
Stage	
I	81 (51.3)
II	65 (41.1)
III	12 (7.6)
Tumor bed boots radiotherapy	
No	18 (11.4)
Yes	140 (88.6)

Table 1:
Patient, tumor and treatment characteristics (Continued)

Characteristics	n (%)
Chemotherapy	
No	41 (25.9)
Yes	117 (74.1)
Endocrine therapy	
No	40 (25.3)
Yes	118 (74.7)
Target therapy	
No	152 (96.2)
Yes	6 (3.8)

Five-year overall and disease-free survivals were 100% and 97.8%, respectively, with 10-year overall survival and disease-free survival were 100% and 95.7%, respectively as presented in Figure 1.

On univariate analysis, the factors that affected the DFS were the number of involved axillary lymph nodes more than 4 (p= 0.011) and Her-2 positive (p= 0.03). However, on multivariate analysis, only the number of involved axillary lymph nodes more than 4 (Hazard ratio (HR) of 10.25; 95% CI:1.66-63.18) affected the DFS as shown in Table 2.

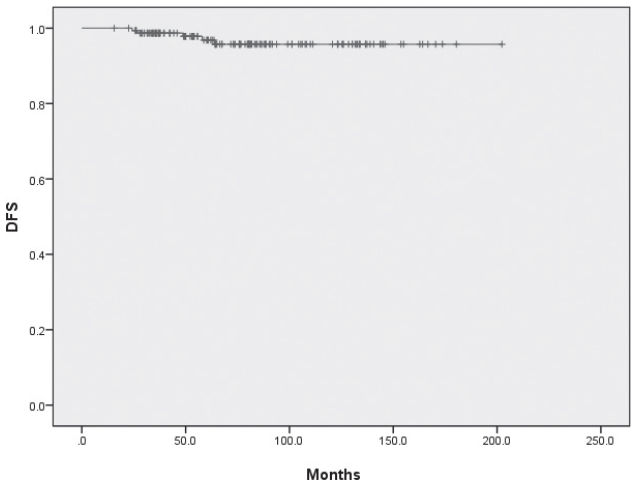

Figure 1: Disease-free survival of breast conservative treatment

Table 2:

Factors affected DFS: univariate and multivariate analysis

Characteristics	Univariate analysis			Multivariate analysis		
	p-value	HR	95%CI	p-value	HR	95%CI
Age (<45 years vs. ≥45 years)	0.384	0.46	(0.08-2.76)			
Axillary surgery (SLNB vs. AXND)	0.247	70.55	(0.53-94441.70)			
Margin status (negative vs. positive)	0.637	0.09	(0.00-1594.89)			
Histologic type (IDC vs. other)	0.945	0.91	(0.06-15.05)			
Histologic grade (I&II vs. III)	0.221	194.87	(0.42-898581.77)			
LVI (not preset vs present)	0.173	3.91	(0.55-27.79)			
Hormonal status (negative vs. positive)	0.34	0.39	(0.05-2.73)			
Her-2 status (negative vs. positive)	0,030	1.99	(1.07-3.69)	0.06	2.11	(0.97-4.26)
Ki 67 index (< 14 % vs. ≥ 14 %)	0.625	56.29	(0.00-584759614.12)			
Tumor size (≤5 cm vs. >5 cm)	0.785	0.047	(0.00-167.80)			
Number of positive nodes (<4 vs. ≥4)	0.011	10.3	(0.72-61.79)	0.012	10.25	(1.66-63.18)
Tumor bed boost (no vs. yes)	0.719	0.67	(0.07-6.00)			
Chemotherapy treatment (no vs. yes)	0.819	1.29	(0.14-11.57)			
Hormonal Rx (no vs. yes)	0.509	0.55	(0.09-3.28)			
Targeted therapy treatment (no vs. yes)	0.818	0.05	(0.00-10.11)			

Discussion

In the present study, the authors focused on the patients-tumor characteristics and outcomes of breast cancer patients treated with BCT. BCT has been increasingly treated as an alternative to mastectomy in specific patients, as it provides tumor removal while maintaining an acceptable cosmetic outcome, fewer complications, and a better quality of life. The 5-year and 10-year DFS rates in our study were 97.8% and 95.7% whereas the 5-year and 10-year OS rates were 100% and 100%. These rates were in the ranges which were reported in the NSABP B06[8] and another studies[9-13]. The long-term analysis of this study demonstrated that the DFS and OS were rather stable after 5 years. Several studies reported a recurrence rate in the range between 3-22%[11-15] that was consistent with this study of 3 percent recurrence rate.

An increasing number of studies have shown improved overall survival among women treated with BCT regardless of cancer phenotype compared with mastectomy[11-17]. Lagendijk M et al. showed that BCT roughly 25% better OS than mastectomy[16]. This was consistent when comparing the OS of BCT in this study with the mastectomy in a study the authors had previously reported[18]. Our results further support the hypothesis that BCT might be the preferred choice for breast cancer patients when both BCT and mastectomy are a suitable treatment options.

Another important aspect of the BCT was the identification of the risk factors for disease recurrence. Several studies have suggested that young age is a risk factor for recurrence[19-23], whereas other have not[24-25]. We did not find that younger age associated with disease recurrence in our study.

Lymph node status was the main prognostic factor that affects the outcome of breast cancer. NSBP trials[8] showed patients with four or more node metastases had significantly worse DFS than those who had no node metastases or to three-node metastases. The present result was similar to the above-mentioned reports.

Several reports have suggested that the histologic features: aggressive cell type, high tumor grade, present LVI, large tumor size, positive margin, poor histochemistry status and adjuvant treatment may contribute to the increased recurrence rates[20-21,26-28]. We did not encounter aggressive cell type, high tumor grade, present LVI, large tumor size, positive margin, poor histochemistry status, and adjuvant treatment as described in some studies associated with a higher recurrence rate.

Conclusion

BCT being at least equivalent in outcome to MRM achieves good long-term survival with reduced local morbidity. Patients who are suitable for BCT should be advised that BCT is the best treatment option for them. The treatment should be decided upon according to the risk of relapse for the patient and the possibility of improved disease control and survival by the treatment. In our study, the number of involved lymph nodes was the important prognostic factor affecting disease-free survival. Therefore, patients with positive lymph nodes should be treated aggressively and patients without risk factors may require less aggressive treatment.

Ethics approval

This study was conducted with the approval of the institutional review board of the Faculty of Medicine Vajira Hospital, Navamindradhiraj University (COA 084/2561).

Disclosure statement

The authors report no conflict of interest.

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Diagnostic Accuracy of the Liver Imaging Reporting and Data System (LI-RADS 2018) in Diagnostic of Hepatocellular Carcinoma in Cirrhosis Patients, Chronic Hepatitis B Carrier Patient, Prior Hepatocellular Carcinoma Patient and Treated Hepatocellular Carcinoma Patient Compared with Histopathological Report

Monthanee Puengphong MD[1]
Krongkan Kanchanarat MD[1*]

[1] Department of Radiology, Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand
* Corresponding author, e-mail address: krongkan@nmu.ac.th
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Abstract

Objective: To evaluate the accuracy of the Liver Imaging Reporting and Data System (LI-RADS) version 2018 category 5 in magnetic resonance imaging (MRI) for the diagnosis of hepatocellular carcinoma

Methods: This retrospective study included patients who underwent liver MRI and had proven pathological lesion. From 2012 to 2021, 45 patients (52 observations including 29 HCCs) met the inclusion criteria. Two radiologists independently reviewed hepatic observation and assessed the LI-RADS version 2018 category. The diagnosis performances of LI-RADS 3, LI-RADS 4, and LI-RADS 5 were calculated using the generalized estimating equation method.

Results: A total of 45 patients (mean age, 59.8) with 52 lesions, including 26 men and 19 women met the inclusion criteria. Most lesions were HCC ,29 (55.8%). The highest sensitivity of the major feature for HCC diagnosis was non-rim arterial enhancement (93%). The highest specificity of the major feature for HCC diagnosis was capsule appearance (100%). The highest accuracy of the major feature for diagnosis was non-rim peripheral washout (86.6%). The inter-observer agreement between the two readers in the classification of lesions was perfect for the Liver Imaging Reporting and Data System (LI-RADS) classification (k= 0.868) and almost perfect for LI-RADS with AF classification (k= 0.872). The LI-RADS 5 sensitivities were 82.8% and 79.3% (as R1, R2) with the same value when combined with ancillary findings. The accuracy of L5 of LI-RADS 2018 was 87.5% (same value with ancillary findings) and 83.3% (same value with ancillary findings) in R1 and R2, respectively.

Conclusion: The LI-RADS version 2018 category 5 has high sensitivity, specificity, and accuracy in the diagnosis of HCC.

Keywords: LIRAD, LIRAD version 2018, HCC

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ความถูกต้องในการใช้ liver imaging reporting and data system ฉบับ 2018 (LI-RADS version 2018) ในการวินิจฉัยมะเร็งตับในผู้ป่วยที่มีภาวะตับแข็ง, ผู้ป่วยที่มีภาวะพาหะตับอักเสบบี เรื้อรัง, ผู้ป่วยที่เคยเป็นมะเร็งตับมาก่อนและรักษาแล้ว จากภาพเอกซเรย์สนามแม่เหล็กไฟฟ้า เปรียบเทียบกับผลชิ้นเนื้อ

มณฑนีย์ พึ่งพงษ์ พ.บ.[1]

กรองกาญจน์ กาญจนรัตน์ พ.บ.[1*]

[1] ภาควิชารังสีวิทยา คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย

* ผู้ติดต่อ, อีเมล: krongkan@nmu.ac.th

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บทคัดย่อ

วัตถุประสงค์: ประเมินความแม่นยำของ LI-RADS ฉบับ 2018 ระดับ 5 ในภาพคลื่นสนามแม่เหล็กไฟฟ้าในการวินิจฉัยมะเร็งตับ

วิธีดำเนินการวิจัย: เป็นการศึกษาย้อนหลัง ผู้ป่วยที่ได้รับการตรวจภาพรังสีวินิจฉัยสนามแม่เหล็กไฟฟ้าของตับและมีรอยโรคทางพยาธิวิทยาที่พิสูจน์แล้วตั้งแต่ปี ค.ศ. 2012 to 2021 จำนวน 45 คน (52 รอยโรค, มะเร็งตับ 29 รอยโรค) รังสีแพทย์ 2 คนประเมินระดับของ LI-RADS ฉบับ 2018 ในแต่ละรอยโรค ผลวินิจฉัย LI-RADS ระดับ 3 ถึง 5 คำนวณโดยใช้ generalized estimating equation method.

ผลการวิจัย: ผู้ป่วย 45 คน (อายุเฉลี่ย 59.8 ปี) 52 รอยโรค ชาย 26 คน, หญิง 19 คน ส่วนใหญ่ของรอยโรคเป็นมะเร็งตับ, 29 (ร้อยละ 58.8) Major feature ที่มีความไวสุดในการวินิจฉัยมะเร็งตับ คือ non- rim arterial enhancedment (ร้อยละ 93) Major feature ที่มีความจำเพาะสุดในการวินิจฉัยมะเร็งตับคือการมี capsule (ร้อยละ 100) Major feature ที่มีความแม่นยำสุดในการวินิจฉัยมะเร็งตับ คือ non-rim peripheral washout (ร้อยละ 86.6). Inter-observer agreement ของรังสีแพทย์ 2 คนในการจำแนกรอยโรคโดยใช้ LI-RADS ฉบับ 2018 มีความสมบูรณ์แบบ (k = 0.868) และเกือบจะสมบูรณ์แบบเมื่อร่วมกับ ancillary findings (k = 0.872) ความไวของ LI-RADS ฉบับ 2018 ระดับ 5 ในการวินิจฉัย HCC เท่ากับ ร้อยละ 82.8 และ ร้อยละ 79.3 (รังสีแพทย์คนที่1, 2) โดยมีค่าเดียวกันเมื่อใช้ร่วมกับ ancillary findings ความแม่นยำของ LI-RADS ฉบับ 2018 ระดับ 5 ในการวินิจฉัยมะเร็งตับเท่ากับ ร้อยละ 87.5 และ ร้อยละ 83.3 (รังสีแพทย์คนที่ 1, 2) โดยมีค่าเดียวกันเมื่อใช้ร่วมกับ ancillary findings

สรุป: LI-RADS ฉบับ 2018 ระดับ 5 มีความไวและความแม่นยำสูงในการวินิจฉัยมะเร็งตับ

คำสำคัญ: LIRAD, LI-RADS ฉบับ 2018, มะเร็งตับ

วันที่รับบทความ 30 ธันวาคม 2564 **วันแก้ไขบทความ** 21 มีนาคม 2565 **วันตอบรับบทความ** 7 เมษายน 2565

Introduction

In 2020, liver cancer was the sixth leading cause of death globally (30160 individuals), in which the most common cause was lung cancer (135,720 individuals)[1]. The most frequent primary malignant tumor of the liver is hepatocellular carcinoma (HCC), which is the second leading cause of cancer-related death globally[2]. Hepatitis B and C viruses (HBV and HCV) are the important risk factors for HCC development and account more than 80% of HCC cases worldwide[3]. In a cancer institute in Thailand, in 2013–2015, the incidence of liver cancer was 33.9% in men and 12.9% in women. In 2018, liver cancer was noted in 18.2% of all cancers in men, which was the second most common cancer after colonic cancer (19.7%). In women, liver cancer was noted in 4.4% which was the sixth most common cancer in women[4]. Liver cancer is divided into three types: 1. Hepatocellular carcinoma (HCC), which is caused by the liver cell and is the most common, more than 80% of all liver cancers 2. Intrahepatic bile duct cancer, which is the most common liver cancer in northeast Thailand and caused by liver fluke and 3. other liver cancer types, such as lymphoma, angiosarcoma, and metastatic liver cancer.

To date, imaging, particularly multiphasic contrast-enhanced CT and MRI, is critical in the diagnosis of HCC. In high-risk patients, hepatocelluar carcinoma (HCC) is the only primary malignancy that can be identified with imaging alone, without the need for pathologic confirmation. As a result, acceptable imaging criteria for noninvasive HCC diagnosis are critical.

The LI-RADS is a classification system for liver lesion that is used in patients with liver cirrhosis and hepatitis B carriers because these patients are at higher risk of HCC. The LI-RADS category indicates the probability of HCC which is based on typical CT and MRI findings. However the LI-RADS is not used in patients aged less than 18 years or those with cirrhosis due to congenital fibrosis or vascular disorder because these groups of patients have low risk of developing HCC. The LI-RADS was introduced in 2011 and has been upgraded four times since then: 2013, 2014, 2017, and 2018. In our study, we used LI-RADS version 2018, which has two revised points: 1.Threshold growth definition was simplified to greater than or equal to 50% increase in the size of a mass in less than or equal to 6 months, in which the rationale is simply to achieve concordance with the definition advocated by the American Association for the Study of Liver Diseases (AASLD) and Organ Procurement and Transplantation Network (OPTN). Now, AASLD, OPTN, and LI-RADS have the same definition for threshold growth. 2. LI-RADS 2018 category 5 (LR5) criteria were revised to match those advocated by the AASLD. The - g and -us designations were eliminated for simplicity.

The rationale is simple. It has closer concordance with AASLD and OPTN criteria. Presently, LI-RADS and AASLD have the same criteria for definite HCC, and LI-RADS and OPTN have almost identical criteria for HCC with one exception: 10–19 mm + arterial phase hyperenhancement (APHE) + non peripheral washout = LR5 but does not meet OPTN class 5 criteria[5].

A study of 70 patients from China (2020) by Shuo et al. found that the use of LR5 had 94% sensitivity for HCC[6]. A systematic review by Lee et al. from Korea (2020), with a total of 14 studies and 1841 HCC lesions, using LR5 showed 70% sensitivity for HCC (95% CI, 61–78), LR4 had 64% sensitivity for HCC (95% CI, 47–80), and LR3 had 31% sensitivity for HCC (95% CI, 12–50)[7]. The used of LI-RADS version 2018 criteria, which were referenced from two studies from China and Korea, revealed the difference in sensitivity. Moreover, the faculty of Medicine Vajira Hospital had performed MRI of a patient with suspected liver cancer since 2010.

Until now, hepatobiliary specific contrast agent for increased MRI detection of focal liver lesion and LI-RADS had never been used in the diagnosis of liver cancer in these patients. Therefore, we aimed to evaluate the accuracy of LR5 in the diagnosis of HCC compared with histopathological report.

Methods

Study population

This retrospective study was approved by the institutional review board of our institution and performed at a tertiary academic medical center. Informed consent was waived due to the retrospective nature of medical records and imaging. We searched the electronic medical record of our institution from 2012 to 2021. We found 84 patients with cirrhosis, chronic hepatitis B carrier, prior hepatocellular carcinoma and treated hepatocellular carcinoma underwent MRI study. Finally we identified 45 patients who met the inclusion criteria. The inclusion criteria were as follows: 1) The population underwent MRI with hepatobiliary specific contrast agent for suspected liver lesion. 2) The patient who had cirrhosis, chronic hepatitis B, previous HCC, and treated HCC underwent MRI. 3) All patients had tissue pathological report. 4) All patients underwent AFP blood test. The exclusion criterion was that the patient did not receive surgery.

Definition

The LI-RADS categories were as follows: LI-RADS 1, definitely benign; LI-RADS 2, probably benign; LI-RADS 3, intermediate probability; LI-RADS 4, probably HCC;LI-RADS 5, definitely HCC , LI-RADS TIV, and LI-RADS M. Five major features are typically observed in HCC in patients with liver cirrhosis and chronic HBV infection: 1. arterial phase hyperenhancement (APHE), 2. nonperipheral washout, 3. capsule, 4. size, 5. threshold growth. There are also ancillary features that are helpful in the detection, improvement, and increased confidence in the diagnosis of HCC. Ancillary features that favor HCC are non-enhancing capsule, nodule within nodule, mosaic structure, blood product in mass, and fat in mass. Ancillary features that favor malignancy (not HCC) are restriction diffusion, mild–moderate T2 hyperintensity, coronal enhancement, fat sparing in solid mass, iron sparing in solid mass, transitional phase hypointensity, and hepatobiliary phase hypointensity. Ancillary features that favor benignity are parallel blood pool, undistorted vessels, higher iron level in the mass than in the liver, marked T2 hyperintensity, and hepatobiliary phase isointensity[5].

MRI

Dynamic contrast-enhanced MRI of the liver was performed with 1.5 or 3.0 Tesla using 0.1 mL/kg or 10 mL of gadoxetate disodium (Primovist). The injection rate was 1 mL/s, followed by 10–20 mL of NSS. MRI technique are T1-weighted imaging (in phased and opposed phase), T2-weighted imaging, diffusion weighted imaging (DWI), and apparent diffusion coefficient imaging. Dynamic imaging was performed at 25, 75, and 120 s. Hepatobiliary phase was applied at 3,5,10, and 20 min.

Imaging review

The MR images were reviewed on Picture Archiving and Communication System (PACS) by two radiologists with 10 years' and 8 years' experience. The two radiologists were blinded to the histopathological report, but they aware of the purpose of the study. The patient's age, sex, AFP level, and histopathological report were collected by one radiologist and shared with the other. They reviewed the presence of major and ancillary features of the observation.

The major features were as follows: 1) arterial phase hyperenhancement, which were categorized as < 10 mm, 10–19 mm, and ≥ 20 mm, 2) nonperipheral washout area, 3) presence of capsule, and 4) threshold growth. The threshold growth was not accessed in our study because only one review was evaluated per patient. If the observation enhancement was not arterial phase hyperenhancement, they were arterial phase hypoenhancement or isoenhancement, which were categorized as <20 mm and ≥ 20 mm, respectively. The ancillary findings favored HCC, malignancy (not HCC), and benignity. 1) Findings that favored HCC are nonenhancing capsule, nodule within nodule, mosaic structure, blood product in the mass, and fat in mass. 2) Findings that favored malignancy (not HCC) are restriction diffusion, mild–moderate T2 hyperintensity, coronal enhancement, fat sparing in solid mass, iron sparing in solid mass, transitional phase hypointensity, and hepatobiliary phase hypointensity. 3) Findings that favored benignity are parallel blood pool, undistorted vessels, higher iron level in the mass than in the liver, marked T2 hyperintensity, and hepatobiliary phase isointensity. The LI-RADS category was assessed using CT/MRI diagnostic table[5]. The ancillary findings were applied as follows: [5] If ancillary findings favored malignancy, upgrade by 1 category to LR4; however, absence of these ancillary findings should not be used to downgrade. If ancillary findings favored benignity, downgrade by 1 category; however absence of these ancillary findings should not be used to upgrade. If ancillary findings favored malignancy and ancillary findings favored benignity, do not adjust category. Moreover, the ancillary findings features cannot be used to upgrade to LR5.

Statistical analysis

The patients and lesion characteristic data were summarized using descriptive statistics. Continuous data are presented as mean ± standard deviation or median range, and categorical data are presented as frequency and percentage. Diagnostic performance values were reported as sensitivity, specificity, positive predictive value, negative predictive value, and accuracy. The chi-square test was used to analyze the association between AFP and HCC. Inter-observer agreement between the two readers was evaluated using Cohen's kappa with 95% confidence intervals. Agreement level was interpreted as slight (kappa = 0.01–0.20), fair (kappa= 0.21–0.40), moderate (kappa = 0.41–0.60), substantial (kappa = 0.61–0.80), or almost perfect or perfect (kappa = 0.81–1.00). A P-value < 0.05 was considered statistically significant. Analyses were performed using PASW Statistics (SPSS) 18.0 (SPSS Inc., Chicago, IL, USA). To interpret the Cohen's kappa results, refer to the following guidelines (see Landis, JR & Koch, GG (1977). The measurement of observer agreement for categorical data. Biometrics, 33, 159-174).

Results

A total of 45 patients (mean age, 59.8 ± 13.7 years; range, 30–90 years) with 52 lesions, including 26 (57.8%) men and 19 (42.2%) women, were selected for the analysis. The median AFP level of the lesion was 5.8 ng/mL (range, 1–12, 174 ng/mL). Most of the 52 lesions were HCCs (55.8%). The other lesions were cholangiocarcinoma (1,1.9%), focal nodular hyperplasia (3, 5.8%), fibrosis (1, 1.9%), hemangioma (3, 5.8%), hepatitis (3, 5.8%), metastases (1, 1.9%), and others (11, 21.2%). The other lesions were fatty liver(2), cirrhosis, granuloma(2), hepatic adenoma(2), hepatic lymphoma(2), EBV infection, cirrhotic nodule. Regarding the association between AFP and HCC, the proportion of HCC was 93.3% in

patients with AFP level > 10 ng/mL and 38.5% in patients with AFP level ≤ 10 ng/mL. Thus, there was a statistically significant association between AFP level and HCC (P = 0.001). Regarding the frequencies of HCC and non-HCC by LI-RADS classification and LI-RADS with AF classification in the two readers, when major features were reviewed by reader 1, HCC was diagnosed in 1 of 8 (12.5%) LR3 lesions, 4 of 15 (26.7%) LR4, and 24 of 25 (96%) of LR5. Moreover, when the major features and AF were combined, HCC was diagnosed in 0 of 4 (0.0%) LR3 lesions, 5 of 19 (26.2%) of LR4, and 24 of 25 (96%) of LR5. The percentage of HCC in reader 2 for categories LR3, LR4, and LR5 were 22.2%, 28.6%, and 92%, respectively, for LI-RADS classification and 0%, 31.6%, and 92% for LI-RADS with AF classification. Regarding diagnostic performance for each major feature finding, sensitivity of major feature for diagnosis of HCC ranged from 7.1% to 93.3% and was highest for non-rim arterial enhancement. The specificity of major feature ranged from 17.4% to 100.0% and was highest for capsule appearance. Positive predictive value ranged from 18.2% to 100.0% and was highest for capsule appearance. Negative predictive value ranged from 29.7% to 100.0% and was highest for enhancement. Accuracy ranged from 27.1% to 86.6% and was highest for non-rim peripheral washout. The two readers' agreement in major finding ranged from substantial to perfect agreement (Kappa = 0.78 to 1.00). The percentage of diagnosis of HCC in the ancillary feature favored HCC was 100% HCC in both readers 1 and 2, which was highest for non- enhancing capsule (90% in Reader 1 and 77.8% in Reader 2). The percentages of diagnosis of HCC in the ancillary feature in favor of malignancy (not HCC) were 59.2% in reader 1 and 62.2% in reader 2, while other malignancies were 4% and 4.4% in reader 1 and reader 2. No LR M and LR TIV were categorized in our study as one metastasis was categorized as LR5 and another one of cholangiocarcinoma was categorized as LR4. As a study of 70 patients from China (2020) by Shuo et al. found that LI-RADS 2018 category 5 (LR5) had 94% sensitivity for HCC[6] and a systematic review by Lee et al from Korea (2020)[7] in which the LR5 had 70% sensitivity in the diagnosis of HCC (95%, 61–78), LR4 had 64% sensitivity (95% CI, 47–80), LR3 had 31% sensitivity (95%CI, 12–50).

Our study revealed that, in LI-RADS 2018, LR5 had sensitivity of 82.8% and 79.3% in diagnosis of HCC (as R1, R2) with the same sensitivity when combined with ancillary findings (82.8%, 79.3%) and specificity 94.7% and 89.5% in diagnosis of HCC (as R1, R2) and the same specificity when combined with ancillary findings as 94.7% and 89.5%, respectively (Table 1).

In our result study, in LI-RADS 2018, LR5 sensitivity was 82.8% and 79.3% (as R1, R2) and the same value when combined with ancillary findings. This value was between the sensitivity of 70% of a systematic review by Lee et al.[7] and sensitivity of 94% of Shao et al[6] . The accuracy of L5 of LI-RADS 2018 was 87.5% (same value with ancillary findings) and 83.3% (same value with ancillary findings) in R1 and R2, respectively.

LR4 had sensitivity of 13.8% (17.2% with AF), 13.8% (20.7% with AFs) in R1 and R2 and had specificity of 42.1% (26.3% with AFs) and 47.4% (31.6% with AF) in R1 and R2, respectively. The accuracies of LR4 in diagnosis HCC were 25% (20.8% with AF) and 27.1% (25% with AF) in R1 and R2 (Table 2). LR3 had sensitivity of 3.4% (0% with AF) and 6.9% (0% with AF) and had specificity 63.2% (79% with AF) and 63.2% (79% with AF) in R1 and R2, respectively. The accuracy of LR3 was 27.1% (31.3% with AF) and 29.3% (31.3% with AF) in R1 and R2 (Table 3). The inter-observer agreement between the two readers in the categorical classification of lesions was perfect for the LI-RADS classification (kappa = 0.868; 95% CI, 0.735–1.000) and almost perfect for LI-RADS with AF classification (kappa = 0.872; 95%CI, 0.747–0.997).

Table 1:

Diagnostic performance of LI-RADS5 and LI-RADS5 with AF

Parameter	Reader1		Reader2	
	LI-RADS5	LI-RADS5 with AF	LI-RADS5	LI-RADS5 with AF
True positive	24	24	23	23
False negative	5	5	6	6
False positive	1	1	2	2
True negative	18	18	17	17
Sensitivity, % (95% CI)	82.8% (64.2%, 94.2%)	82.8% (64.2%, 94.2%)	79.3% (60.3%, 92.0%)	79.3% (60.3%, 92.0%)
Specificity, % (95% CI)	94.7% (74.0%, 99.9%)	94.7% (74.0%, 99.9%)	89.5% (66.9%, 98.7%)	89.5% (66.9%, 98.7%)
Positive predictive value, % (95% CI)	96.0% 78.0%, 99.4%)	96.0% 78.0%, 99.4%)	92.0% (75.4%, 97.7%)	92.0% (75.4%, 97.7%)
Negative predictive value, % (95% CI)	78.3% (61.7%, 89.0%)	78.3% (61.7%, 89.0%)	73.9% (57.8%, 85.5%)	73.9% (57.8%, 85.5%)
Accuracy, % (95% CI)	87.5% (74.8%, 95.3%)	87.5% (74.8%, 95.3%)	83.3% (69.8%, 92.5%)	83.3% (69.8%, 92.5%)

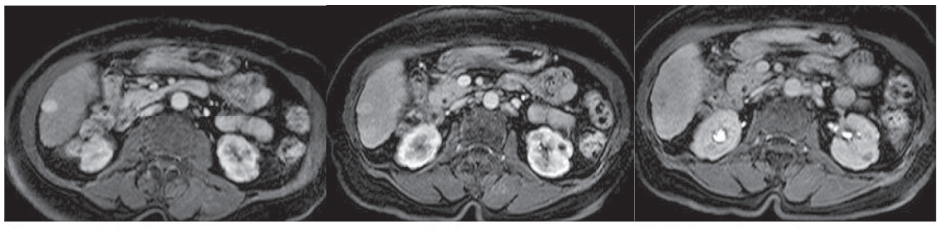
Table 2:

Diagnostic performance of LI-RAD4 and LI-RAD4 with AF

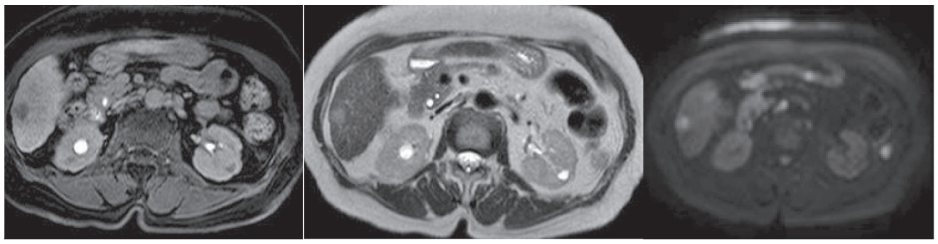
Parameter	Reader1		Reader2	
	LI-RAD4	LI-RAD4 with AF	LI-RAD4	LI-RAD4 with AF
True positive	4	5	4	6
False negative	25	24	25	23
False positive	11	14	10	13
True negative	8	5	9	6
Sensitivity, % (95% CI)	13.8% (3.9%, 31.7%)	17.2% (5.9%, 35.8%)	13.8% (3.9%, 31.7%)	20.7% (8.0%, 39.7%)
Specificity, % (95% CI)	42.1% (20.3%, 66.5%)	26.3% (9.2%, 51.2%)	47.4% (24.5%, 71.1%)	31.6% (12.6%, 56.6%)
Positive predictive value, % (95% CI)	26.7% (11.9%, 49.4%)	26.3% (13.3%, 45.3%)	28.6% (12.8%, 52.2%)	31.6% (17.5%, 50.1%)
Negative predictive value, % (95% CI)	24.2% (15.6%, 35.6%)	17.2% (8.8%, 31.0%)	26.5% (18.0%, 37.2%)	20.7% (11.6%, 34.2%)
Accuracy, % (95% CI)	25.0% (13.6%, 39.6%)	20.8% (10.5%, 35.0%)	27.1% (15.3%, 41.9%)	25.0% (13.6%, 39.6%)

Table 3:
Diagnostic performance of LI-RADS3 and LI-RADS3 with AF

Parameter	Reader1		Reader2	
	LI-RADS3	LI-RADS3 with AF	LI-RADS3	LI-RADS3 with AF
True positive	1	0	2	0
False negative	28	29	27	29
False positive	7	4	7	4
True negative	12	15	12	15
Sensitivity, % (95% CI)	3.4% (0.1%, 17.8%)	0.0% (0.0%, 11.9%)	6.9% (0.9%, 22.8%)	0.0% (0.0%, 11.9%)
Specificity, % (95% CI)	63.2% (38.4%, 83.7%)	79.0% (54.4%, 94.0%)	63.2% (38.4%, 83.7%)	79.0% (54.4%, 94.0%)
Positive predictive value, % (95% CI)	12.5% (1.9%, 51.7%)	0.0% (0.0%, 60.2%)	22.2% (6.2%, 55.2%)	0.0% (0.0%, 60.2%)
Negative predictive value, % (95% CI)	30.0% (23.2%, 37.8%)	34.1% (29.1%, 39.5%)	30.8% (23.7%, 38.9%)	34.1% (29.1%, 39.5%)
Accuracy, % (95% CI)	27.1% (15.3%, 41.9%)	31.3% (18.7%, 46.3%)	29.2% (17.0%, 44.1%)	31.3% (18.7%, 46.3%)



A arterial phase B portal phase C delayed 5 minutes



D delayed 20 minutes F T2-weighted image G diffusion weighted image

Figure 1: Axial imaged of gadoxedate -enhancedment MRI in a 71- year-old woman with hepatitis B and hepatocellular carcinoma at segment 6. The liver mass at segment 6 measuring 1.5×1.4 cm in size showed hypersignal intensity on T2 weight (E), arterial phase (A) hyperenhancement, washout on portal phase (B) with enhancing capsule. The mass showed restriction (F) on DWI, hyposignal intensity on transitional phase (C) and delayed 20 minutes image (D). This hepatic observation was categorized as LR 5 according to LIRAD version 2018. HCC was confirmed with pathological report.

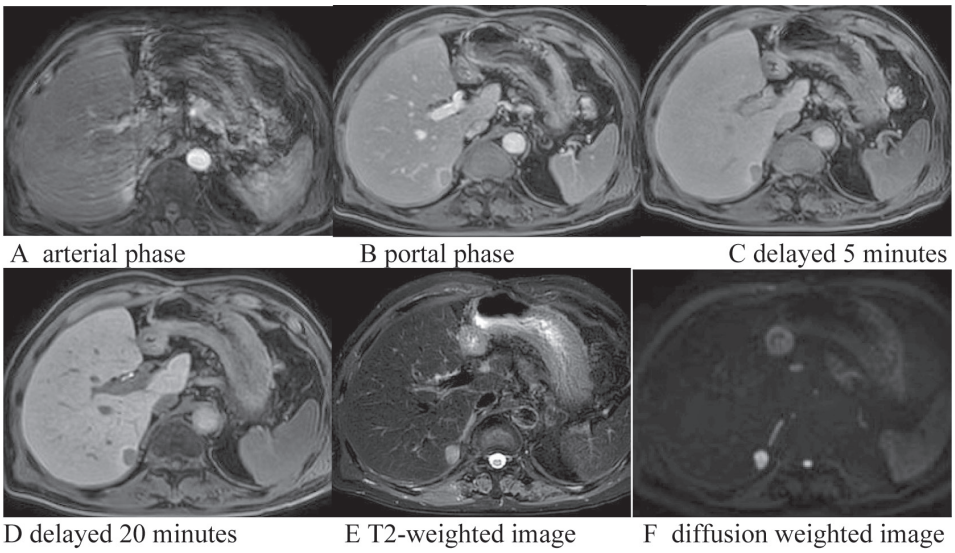


Figure 2: Axial imaged of gadoxedate -enhancedment MRI in a 90 - year-old man with chronic hepatitis B and hepatocellular carcinoma (HCC) at segment 6. The liver mass at segment 6 of liver measuring 1.3x1.3 cm in size showed hypersignal intensity on T2 weight (E), arterial phase (A) hyperenhancedment, washout on portal phase (B) with visible enhancing capsule. The mass showed restriction (F) on DWI, hyposignal intensity on transitional phase (C) and delayed 20 minutes image (D). This hepatic observation was categorized as LR 5 according to LIRAD version 2018. HCC was confirmed with pathological report. Also noted motion artifact on arterial phase image (A).

Discussion

Our study showed sensitivity of 82.8% (same value with AF) and specificity of 94.7% for HCC diagnosis in LR5 category (Table 1) in reader 1, 79.3% (same value with AF) sensitivity, and 89.5% (same value with AF) specificity in reader 2. This showed high sensitivity and high specificity of LR5 in diagnosis of HCC (Table 1).

The same sensitivity and specificity of LR5 and LR5 with AF in readers 1 and 2 were because there was no upgrade or downgrade of LR5. The LR5 showed more percentage of HCC than LR4 (96% LR5 and 26.7% LR4 as reader 1 without AF). Our study revealed that, in LI-RADS 2018, LR5 had sensitivity of 82.8% and 79.3% in diagnosis of HCC (as R1, R2) with the same sensitivity when combined with ancillary findings (82.8%, 79.3%) and specificity 94.7% and 89.5% in diagnosis of HCC (as R1, R2) and the same specificity when combined with ancillary findings as 94.7% and 89.5%, respectively (Table 1). The value was between the sensitivity of 70% of a systematic review by Lee et al.[16] and sensitivity of 94% of Shao et al[6].

The LR4 showed more percentage of HCC than LR3 (26.7% LR4 and 12.5% LR3 as reader 1 without AF). Thus, higher LI-RADS showed high percentage of HCC (i.e., 12.5% of LR3, 26.7% of LR4, and 96% of LR5 in reader 1).

LR5 showed higher accuracy than LR4 and LR3 (87.5%, 25%, and 27% as LR5, LR4, and LR3 without AF of reader 1) (83.3%, 27.1%, and 31.3% without AF of reader 2).

In our study, the accuracies of LI-RADS 3 and 4 version 2018 in diagnosis of HCC were 27.1% (31.3% with AF) and 25% (20.8% with AF) (reader 1) and 29.2% (31.3% with AF) and 27.1% (25% with AF) (reader 2). This showed that the accuracy of LR3 and LR4 in the diagnosis of HCC were almost the

same, which could be from a small number of patients. However, the LR5 showed the high accuracy in diagnosis of HCC (87.5%, 25%, and 27% as LR5, LR4, and LR3 without AF of reader 1 and 83.3%, 27.1%, and 31.3% without AF of reader 2). In our study, no LR1 and LR2 were found because, when the criteria met LR1 or LR2 category, the patient did not undergo the procedure to obtain the pathological report. No LR M and LR TIV were categorized in our study. One metastasis was categorized as LR5 and another one of cholangiocarcinoma was categorized as LR4. These could be from small number of patients.

About the major features, the non-rim arterial enhancement (arterial phase hyperenhancement) was more sensitive (93.1%) than other major features for the diagnosis of HCC but the specificity of non-rim arterial enhancement was 52.2%. The non-rim arterial hyperenhancement was noted in 27 HCCs but also observed in 12 non-HCC lesions. The highest specificity of major features was noted in the presence of capsule (100% specificity of R1 and R2), in which its sensitivity was 51.7% in R1 and 55.2% in R2. The capsule was noted in 15 HCC lesions and 0 of non-HCC lesion in R1.

The highest accuracy of major features was noted in non-rim peripheral washout (86.6% R1,80.7% R2) and its sensitivity was 82.8% in R1 and 79.3% in R2. The non-rim peripheral washout was noted in 24 HCCs and two non-HCC lesion (R1). Regarding the ancillary features in favor of HCC, when we concluded finding favored HCC, the histopathological report was HCC totally in both R1 and R2. Moreover, when the conclusion favored malignancy (not HCC), in R1, 29 (59.2%) cases were HCC and 20 (40.8%) were non-HCC, and in R2, 28 (62.2%) cases were HCC, and 17 (37.8%) cases were non-HCC. Moreover, when we concluded finding favored benignity, no HCC was found in both R1 and R2.

Lee et al.[8] and Granata et al[9] reported a sensitivity of 81%–84% and specificity of 73%–100% for hypersignal intensity of DWI. In our study, the highest accuracy of ancillary findings in diagnosis of HCC was noted in non-enhancing capsule (R1 sensitivity 34.5%, specificity 95.7%, and R2 sensitivity, 24.1%, specificity, 91.3%). The highest sensitivity of ancillary findings was noted in hepatobiliary phase hyposignal intensity as 73.9% but the specificity was 6.9%, and the accuracy was 36.5% in R1 (R2 had 65.2% sensitivity, 3,4% specificity, and 30.8% accuracy). The previous studies of LI-RADS version 2014 assessed the application of ancillary features have shown that they modified the final category in 15%–35% of observations with about 63% of LR4 observations being upgraded from LR3[10-12]. In our study, which used the LI-RADS version 2018, the ancillary findings have shown that they modify the final LR category in 36.5% of total observation with 62.5% of LR4 upgraded from LR3 and no LR4 upgrade to LR5 (in reader 1). Moreover, in reader 2, the ancillary findings shown modification of the final LR category in 36.5% of total observation with 66.7% of LR4 upgrade from LR3 and no LR4 upgrade to LR5. The percentage of the upgraded observation was 36.5% as in reader 1 and reader 2 (which was the value about 15%–35% as the previous study[10-12] and the percent upgrade from LR3 to LR4 were 62.5% and 66.7% of readers 1 and 2, respectively, which was about 63% from previous study[10-12].

The limitations of our study were as follows: 1. The retrospective study in one center and more than half of our patients were excluded because they did not met the inclusion criteria. 2. We did not consider the ancillary features in LR TIV and LRM 3. The threshold growth that is one of the major features was not accessed because only one scan was evaluated per patient. 4. The two radiologists were blinded to histopathological report but

they were aware of the purpose of the study. The excluded patients who underwent MRI outside the center with no contrast administration or inadequate quality for evaluation may lead to a selection bias; however, it was necessary for maintenance.

Conclusion

The LI-RADS version 2018 category 5 has high sensitivity (82.8% in R1, 79.3% in R2), specificity (94.7% in R1, 89.5% in R2), and accuracy (87.5% and 83.3% in R1 and R2, respectively) for diagnosis HCC.

Abbreviation

LI-RADS - Liver Imaging Reporting and Data System, TIV -Tumour in vein M - Malignant, HCC - Hepatocellular Carcinoma, AF - Ancillary finding, APHE - Arterial phase hyperenhancement, R1 -Reader 1, R2 -Reader 2.

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Efficacy and Adverse Effects of Sodium Phosphate and Polyethylene Glycol When Used in Bowel Preparation prior to Colonoscopy among Patients Admitted at Vajira Hospital

Thanacom Thapananon MD[1]
Rangsima Thiengthiantham MD[1*]

[1] Surgery Department, Faculty of Medicine, Vajira Hospital, Navamindradhiraj University Bangkok, Thailand
* Corresponding author, e-mail address: rangsima@nmu.ac.th
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Abstract

Objective: Bowel preparation is an important process before colonoscopy. Sodium phosphate (NaP) and polyethylene glycol (PEG) are the drugs mainly used in bowel preparation at Vajira Hospital. Since NaP is an osmotic laxative, it may cause dehydration and electrolyte imbalance. Hence, PEG is commonly utilized in patients admitted to the hospital. The fragile patients need to admitted for bowel preparation for colonoscopy. Thus, the current study aimed to compare the efficacy of NaP and PEG and their effect on electrolyte levels in these patients.

Methods: Datas were collected from admitted patients who received either NaP or PEG for bowel preparation at Vajira Hospital from January 1, 2016, to December 31, 2016.

Results: NaP and PEG did not significantly differ in terms of efficacy. However, compared with PEG, NaP significantly increased serum Na levels (+1.737 mmol/L) and decreased serum K levels (-0.517 mmol/L). Nevertheless, there was no remarkable difference in the changes in serum Na and K levels based on clinical data.

Conclusion: Thus, NaP can be used with caution in bowel preparation among admitted patients as it has minimal side effects on electrolyte levels.

Keywords: bowel preparation, colonoscopy, electrolyte, polyethylene glycol, sodium phosphate

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ความสะอาดของลำไส้และผลข้างเคียงของการใช้ Sodium Phosphate และ Polyethylene Glycol สำหรับเตรียมลำไส้ในผู้ป่วยที่ได้รับการเตรียมลำไส้ใหญ่แบบนอนในวชิรพยาบาล

ธนาคม ฐาปนนนท์ พ.บ.[1]
รังสิมา เที่ยงเธียรธรรม พ.บ.[1*]

[1] หน่วยศัลยกรรมลำไส้ใหญ่และทวารหนัก ภาควิชาศัลยศาสตร์ คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย

* ผู้ติดต่อ, อีเมล: rangsima@nmu.ac.th

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บทคัดย่อ

บทนำ: การเตรียมลำไส้ใหญ่มีความสำคัญต่อการส่องกล้องลำไส้ใหญ่ ยาที่ใช้เป็นหลักในวชิรพยาบาลคือ โซเดียมฟอสเฟต (NaP) และ โพลีเอทธิลีน ไกลคอล (PEG) ซึ่งยา NaP เป็นยากลุ่ม osmotic laxative มีผลข้างเคียงทำให้มีการสูญเสียน้ำและเกลือแร่ จึงมีการใช้ PEG ในโรงพยาบาลเป็นส่วนใหญ่ อย่างไรก็ตามยังไม่มีการศึกษาถึงผลข้างเคียงของ NaP ในผู้ป่วยที่ต้องมีการเตรียมลำไส้ใหญ่ในโรงพยาบาล การศึกษานี้มีจุดประสงค์เพื่อเปรียบเทียบความสะอาดของลำไส้ และผลข้างเคียงจากการเตรียมลำไส้ด้วยตัวยาสองชนิดนี้ในผู้ป่วยที่ต้องอยู่ในโรงพยาบาล

แนวทางวิจัย: การศึกษาย้อนหลังเชิงพรรณนาในผู้ป่วยที่ต้องนอนในวชิรพยาบาลเพื่อเตรียมลำไส้ใหญ่สำหรับการส่องกล้องลำไส้ใหญ่ตั้งแต่วันที่ 1 มกราคม ถึงวันที่ 31 ธันวาคม 2559

ผลของงานวิจัย: ความสะอาดของการเตรียมลำไส้ใหญ่ด้วยยาทั้งสองชนิดไม่แตกต่างกัน แต่ผลข้างเคียงจากการเตรียมลำไส้ใหญ่ด้วย NaP ทำให้มีค่าของโซเดียมและโพแทสเซียมเพิ่มขึ้นและลดลงอย่างมีนัยสำคัญ (+1.737 มิลลิโมล/ลิตร - 0.517 มิลลิโมล/ลิตร) อย่างไรก็ตาม พบว่าค่าผลเลือดที่เพิ่มหรือลดลงจนผิดปกติของทั้งโซเดียมและโพแทสเซียมไม่มีความแตกต่างอย่างมีนัยสำคัญเมื่อเปรียบการเตรียมลำไส้ด้วยยาทั้งสองชนิด

สรุป: การเตรียมลำไส้ด้วย NaP ส่งผลต่อค่าเกลือแร่ในร่างกายเพียงเล็กน้อย และสามารถใช้ได้อย่างปลอดภัยสำหรับผู้ป่วยที่นอนในโรงพยาบาลเพื่อเตรียมลำไส้ใหญ่สำหรับส่องกล้องลำไส้ใหญ่ แต่ควรใช้ด้วยความระมัดระวัง

คำสำคัญ : การเตรียมลำไส้ใหญ่, การส่องกล้องลำไส้ใหญ่, อิเล็กโทรไลท์, โพลีเอทธิลีนไกลคอล, โซเดียมฟอสเฟต

วันที่รับบทความ 15 มิถุนายน 2564 **วันแก้ไขบทความ** 6 เมษายน 2565 **วันตอบรับบทความ** 6 เมษายน 2565

Introduction

Colonoscopy is a diagnostic and therapeutic procedure used to detect colonic lesions such as abnormal vasculature, polyps, and mass. Moreover, polypectomy, biopsy, dilatation, clipping, and electro-cauterization can be conducted via colonoscopy. The American College of Gastroenterology and the Canadian Association of Gastroenterology recommend the use of colonoscopy for screening colonic cancer in normal (age ≥ 50 years old) and high-risk (with first-degree relative with colonic cancer) patients[1]. Since colorectal cancer caused 880,792 deaths in 2018 (9.2% of all cancer-related deaths worldwide)[2], the National Health and Medical Research Council showed that this number can be reduced by 15% with the screening program[3]. Zauber AG revealed that the mortality rate of colorectal cancer decreased by 14% with proper screening and 3% with reduction of risk factors[4].

Nusko et al. showed that if a colonoscopist identifies polyps of the same size, those on the right side of the colon have a higher risk of malignancy than those on the left[5]. Hence, complete colonoscopy is recommended during the screening program. However, a complete colonoscopy cannot be performed in 20%–25% of patients due to inadequate bowel preparation[6-7] owing to bowel habit, drug tolerance, or timing of colonoscopy. People with a history of constipation require a strict dietary program with adequate hydration or adjunct laxative agent. The volume and flavor of drugs may affect patient tolerance. Further, some regimens require a volume intake of up to 4 L, which is sometimes difficult for patients to tolerate. Split-dose regimen on the same day of colonoscopy has better outcomes than that on the day before[7-8]. Thus, adequate bowel preparation has an important role in improving polyp detection rate.

Bowel preparation is composed of dietary program and medications. Patients are advised to take low-residue diet at least 2 days before the procedure date and clear liquid diet 1 day before. By contrast, medications for cleansing the bowel can be divided into four groups, which are as follows: isosmotic, hypoosmotic, hyperosmotic, and combined agents. Isosmotic agent is a non-absorbable solution that contains nonfermentable electrolyte that passes through the bowel without absorption or secretion. Therefore, it is associated with a lower risk of electrolyte imbalance after bowel preparation. Hyposomotic agent is not approved by the Food and Drug Administration for colonoscopy preparation because it has a low adenoma detection rate, and it can cause hyponatremia. Hyperosmotic agent is poorly absorbed, and it is more effective when used for bowel preparation. However, data on its safety are inconclusive. Meanwhile, combined agent is less effective in bowel preparation than isosmotic agent, and it affects the gastrointestinal tract[9].

Two drugs are commonly used for bowel preparation in Vajira Hospital. First is sodium phosphate (NaP), a hyperosmotic agent that may cause dehydration and electrolyte abnormalities or even nephropathy based on several studies[10-11]. However, this agent can be easily used as it can be administered at a low volume. Patients who utilize NaP as a bowel preparation regimen should drink 90 mL of drug in split doses (45 mL each time within a period 4–5 h). The second is polyethylene glycol (PEG), which is an isosmotic agent that has a lesser effect on intravascular fluid and electrolytes[9]. However, patients who take this drug must drink 4 L of water within 2 h as part of the preparation. The use of these drugs is based on the colonoscopist.

Several studies have shown that PEG is safe, and NaP is better for bowel cleansing. However, there is no standard criteria for determining which type of drug should be used particularly in elderly patients and those with several underlying diseases who require close monitoring after fluid loss from diarrhea due to the use of bowel preparation drug. Thus, this study aimed to compare the efficacy of NaP and PEG and their adverse effect on electrolyte levels among admitted patients. Moreover, the most suitable drug for these patients was determined.

Methods

Data were collected from the medical records of patients who were admitted to Vajira Hospital and who underwent colonoscopy from January 1, 2016, to December 31, 2016. Patients who received other laxative drugs and those who had incomplete records were excluded. Demographic data (such as sex, age, weight, height, BMI, duration for complete colonoscopy, current intake of medicine, underlying disease, bowel habit, and indication for colonoscopy) were collected. The Vajira bowel preparation score was used to assess the efficacy of bowel preparation. Vajira bowel preparation is classified into four grades, which were as follows: grade 1, solid feces with bowel wall poorly visualized; grade 2, feces with thick viscosity with bowel wall occasionally seen; grade 3, clear liquid feces with most parts of the bowel wall identified; and grade 4, minimal feces with bowel wall clearly observed. These grades were obtained by the colonoscopist at the time of endoscopy. In terms of serum electrolyte levels, patients who received drugs and 48 hours after received drugs experienced changes in serum sodium (normal range: 135–145 mmol/L) and potassium (normal level: 3.5–5 mmol/L) levels.

Demographic data were presented as percentage, mean, and SD. The Statistical Package for the Social Sciences software version 22.0 (IBM Inc.) was used to compare the efficacy of these drugs and their effect on serum electrolyte levels using the chi-square test and the independent *t*-test. Hazard ratios and 95% confidence intervals were calculated. A P value of <0.05 was considered statistically significant.

Results

Of 214 patients, 95 were included in this study. In total, 61 (64.21%) received NaP for bowel preparation. In the NaP group, 20 (32%) were men. The mean age of the participants was 60.13 (40–85) years; mean BMI, 23.51 (16.23–39.31) kg/m^2; and mean time to finish the procedure, 27.10 (9–45) minutes. About 50% of patients had coronary artery disease. Nearly 15% used nonsteroidal anti-inflammatory drugs or angiotensin-converting-enzyme inhibitors (ACEI)/angiotensin II receptor blockers (ARB). Approximately 30% had constipation and were treated with laxative drugs. However, the most common reason of colonoscopy was the presence of abnormal clinical sign. In about 70% of patients, the scope was passed to the caecum. Then, there were 12 (35%) men in the PEG group. The mean age of the participants was 74.12 (47–94) years; mean BMI, 22.87 (13.67–35.46) kg/m^2; and mean time to finish the procedure, 30.44 (10–60) minutes. Results showed significant differences in terms of age and time to finish the procedure in the NaP group. Moreover, approximately 80% of patients in the PEG group had coronary artery disease. About 25% received ACEI/ARB or diuretic drug. The bowel habit was similar between the PEG and NaP groups. However, the most common cause of colonoscopy was the presence of abnormal clinical signs. The rate of passing the scope to the caecum did not significantly differ between the PEG and NaP groups. One patient in the PEG group presented with bowel perforation (Tables 1A, 1B). Perforated bowel occurred from electrocautery in 79 year old female which underlying hypertension, hyperlipidemia and chronic kidney disease stage III, the cleanliness bowel preparation was good, she had done polypectomy for splenic flexure pedunculated polyp and present clinical abdominal pain 12 hours after intervention. Emergency exploratory and primary repair was done and she was discharged 5 days after operation without any complications. NaP and PEG did not significantly differ in terms of efficacy (Table 2).

NaP increased serum Na levels up to 1.737 mmol/L, which is statistically significant (Figure1, Table 3). Only 11 patients received NaP, and they had high serum Na levels. However, the result did not significantly differ from that of patients who received PEG (Table 4). The maximal level of potassium decreased by NaP was 0.511 mmol/L, which is statistically significant (Figure 2, Table 5). Only 22 patients had low serum K level, and the result did not significantly differ (Table 6).

Table 1:

Demographic data of the patients which bowel preparation prior to colonoscopy in patients admitted at Vajira Hospital

A

Characteristic	NaP Mean (Min–Max, SD)	PEG Mean (Min-Max, SD)	P
Age (y)	60.13 (40-85, 11.40)	74.12 (47-94, 10.08)	.000
BMI (kg/m^2)	23.51 (16.23-39.31, 4.69)	22.87 (13.67-35.46, 5.10)	.543
Duration (min)	27.10 (9-45, 5.91)	30.44 (10-60, 8.45)	.028

B

Characteristic		NaP N = 61 (64.21%)	PEG N = 34 (35.79%)	P
Gender	Male	20 (32.79%)	12 (35.29%)	.807
Current drug	NSAID	8 (13.11%)	2 (5.88%)	.230
	ACEI/ARB	9 (14.75%)	9 (26.47%)	.195
	Diuretic	1 (1.64%)	9 (26.47%)	.003
Underlying	CVS	30 (49.18%)	29 (85.29%)	.000
	Endocrine	14 (22.95%)	10 (29.41%)	.492
	Renal	3 (4.92%)	9 (26.47%)	.012
	GI	2 (3.28%)	0 (0.00%)	.159
Bowel habit	Constipation	21 (34.43%)	11 (32.35%)	.840
	Laxative	19 (31.15%)	10 (29.41%)	.862
Indication	surveillance	31 (50.82%)	7 (20.59%)	.002
	screening	5 (8.21%)	7 (20.59%)	.122
	clinical	25 (40.98%)	20 (58.82%)	.097
Completion		43 (70.49%)	26 (76.47%)	.536
Complication		0 (0.00%)	1 (2.94%)	.325

Table 2:

Efficacy of NaP and PEG for bowel preparation in colonoscopy in admitted patients at Vajira Hospital

Cleanliness	NaP	PEG	Pearson Chi-Square	P
Good (score 4)	44 (72.13%)	29 (85.29%)	2.126	.145
Poor (score 1-3)	17 (27.87%)	5 (14.71%)		

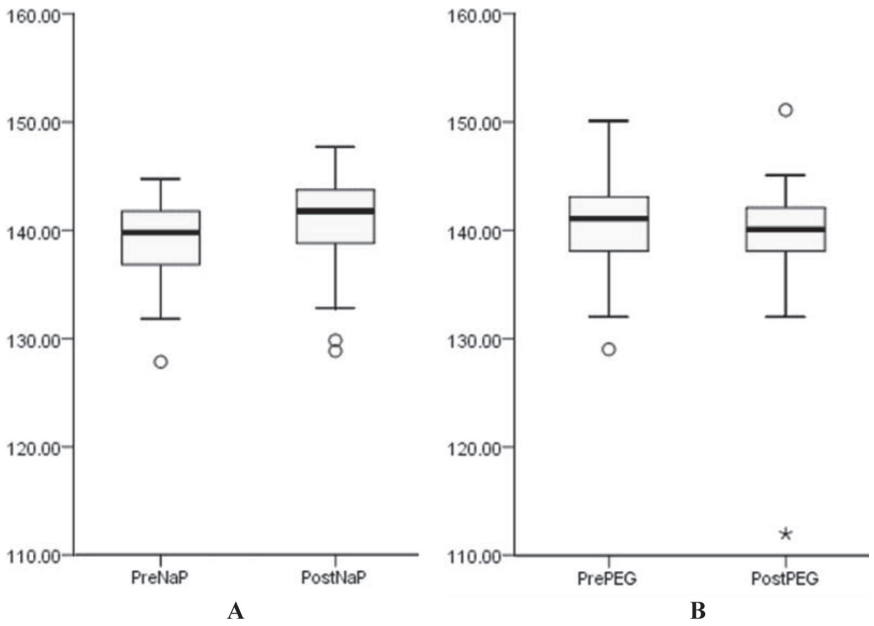

Figure 1: Difference ranges of serum Na levels for pre-bowel preparation with NaP and PEG

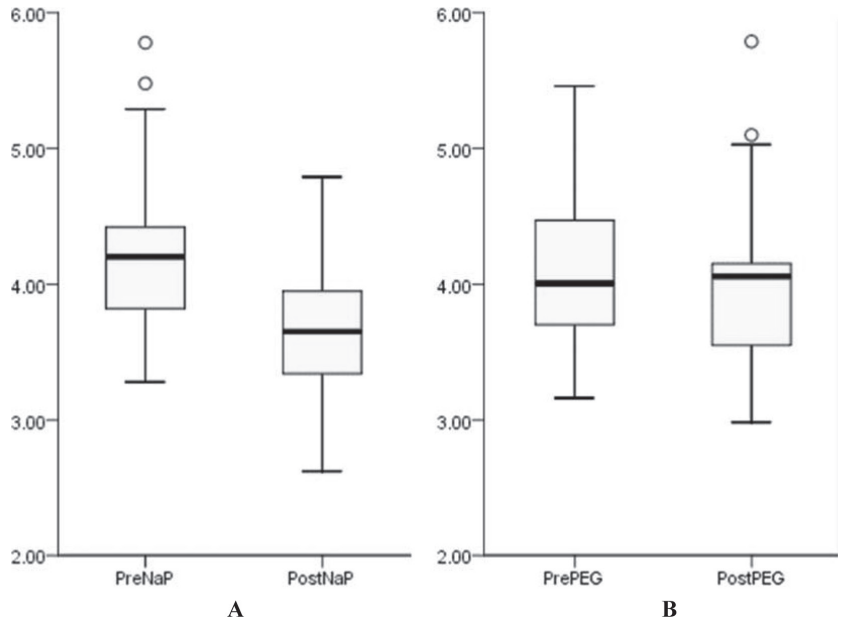

Figure 2: Difference ranges of serum K levels for pre-bowel preparation with and PEG

Table 3:
Number of patients and level change of serum Na

ΔNa	N	Mean	SD	t	Sig
NaP	61	1.737	3.999	2.651	.009
PEG	34	-0.882	5.569		

Table 4:
Number of patients which abnormal change serum Na

ΔNaClinic	N	Mean	SD	t	Sig
NaP	11	2.3636	7.47359	1.382	.190
PEG	4	-5.0000	13.21615		

Table 5:
Number of patients and level change of serum K

ΔK	N	Mean	SD	t	Sig
NaP	61	-0.511	0.536	-3.275	.001
PEG	34	-0.114	0.615		

Table 6:
Number of patients which abnormal change serum K

ΔKClinic	N	Mean	SD	t	Sig
NaP	23	-.7565	.49414	-1.943	.061
PEG	11	-.3373	.75591		

Discussion

Several retrospective studies have shown that NaP has a high efficacy when used in bowel preparation[12–18]. Meanwhile, this research revealed NaP and PEG did not significantly differ in terms of efficacy. Most endoscopist preferred do bowel preparation for fragile patients which inpatients type, for the purpose of early detection and replaced of early rehydration and abnormal electrolyte correction. No standard definition for fragile patients but in practice usually mean old age, multiple comorbidities, impaired kidney function, and the patients who were more likely loss of fluid and abnormality of electrolytes. Our study showed there were statistic significant in term of mean age which higher age and there was statistic significant have cardiovascular disease and renal disease in PEG group which may from individual endoscopist preferred PEG preparation for old age fragile admitted patients which high risk prone to have many complications for bowel preparation.

The recommendation from Kossi et al. showed that the procedure time was shorter in patients who received NaP[17], as shown in this study. Because of the they found statistic significant in term of efficacy bowel preparation in two group that may cause effect for duration colonoscopy. However, the duration for complete colonoscopy was still insignificant for our study.

Several studies have shown that NaP may cause asymptomatic hyperphosphatemia[12,15] and changes in serum electrolyte levels and kidney function without symptom[19]. However NaP associated with symptomatic hyponatremia[20] and nephropathy based on some studies[11,21]. Florentin M et al. revealed that elderly women with metabolic diseases and poor bowel absorption have a higher risk of kidney injuries and hyperphosphatemia[19]. NaP can cause hypocalemia, hypokalemia, hypernatremia, or even hyponatremia caused by dehydration after diarrhea[19]. Moreover, it has a more evident effect on increasing serum Na levels and decreasing serum K levels than PEG. However, the changes did not significantly affect the patients. Nevertheless, changes in serum phosphate levels and kidney function were not assessed in these studies. Thus, clinicians must cautiously consider the risk and benefits of NaP among admitted patients.

This study had several limitations. That is only the bowel cleanliness score in Vajira Hospital was used. Moreover, it has a retrospective design, and most patient data were incomplete, thus we did not collect the changed of other electrolytes such as phosphorous, calcium. Finally, NaP affected to kidney function then monitoring creatinine and kidney function test are important in every status patient especially fragile bowel preparation patients. Another limitation that impact to the adverse effect are age group and the severity of fragile patients, more in PEG group, may be from the bias of endoscopist usually preferred PEG due to less likely have complication in old age and fragile patients. If possible to compare in the likely same characteristic in both group.

Conclusion

The effect of NaP and PEG, which are used in bowel preparation, did not significantly differ in term bowel cleanliness. Compared with PEG, NaP significantly increased serum Na levels and decreased serum K levels. However, based on clinical data, there were no remarkable differences in the changes in serum Na and K levels in selected patients. Thus, NaP can be used for bowel preparation with caution in admitted patients as it has minimal effects on electrolyte levels. The early closed monitoring, rehydration and corrected abnormal electrolytes from timing bowel preparation is important.

Ethical Approval

Committee on Human Rights Related to Research Involving Human Subjects, Faculty of Medicine, Vajira Hospital, Navamindradhiraj University. Protocol Number: ID 036/60 COA 83/ 2560.

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The Correlation between Thai Cardiovascular Risk Score and the Multi-Ethnic Study of Atherosclerosis (MESA) Risk Score in Thai Populations

Kunlatuch Chopchai MD[1]
Chaisiri Wanlapakorn MD[2]
Suwara Issaragrisil MD[3]
Teetouch Ananwattanasuk MD[1]
Padoemwut Teerawongsakul MD[1*]

[1] Division of Cardiology, Department of Medicine, Faculty of Medicine, Navamindradhiraj University, Bangkok, Thailand
[2] Division of Cardiovascular Medicine, Department of Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand
[3] Department of Radiology, Faculty of Medicine, Navamindradhiraj University, Bangkok, Thailand
* Corresponding author, e-mail address: padoemwut@nmu.ac.th
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Abstract

Objective: The purpose of this study was to examine the relationship between the Thai cardiovascular risk score (TCVRS) and the Multi-Ethnic Study of Atherosclerosis (MESA) risk score and predictors of high CAC score in Thai adults without a history of atherosclerotic cardiovascular disease.

Methods: This is a cross-sectional study assessing chest computed tomography scan patients without established atherosclerotic disease in Vajira Hospital, Thailand from July to December 2018. The TCVRS, MESA, and CAC scores were analyzed to estimate coronary heart disease risk. The predictive factors for the high CAC score were assessed by using univariate and multivariable analysis.

Results: The total of 84 patients were enrolled (mean age, 55.1 years and female, 65.5%), mostly zero CAC (46.4%). The correlation of TCVRS and MESA risk score was stronger than FRS and MESA risk score by $r = 0.818$; $p<0.001$ and $r = 0.747$; $p< 0.001$, respectively. The agreements were acceptable with mean difference = -0.73, SD = 0.242 and -3.78, SD = 0.539, respectively. In multivariate analysis, diabetes mellitus (odds ratio [OR]: 28.39, 95% CI:1.92-420.09; $p = 0.015$) and age ≥ 60 years (OR: 38.26, 95% CI:13.76-389.49; $p = 0.002$) were independent risk factors to predict high CAC.

Conclusion: There is a strong correlation between TCVRS and MESA risk score in Thai populations, but the MESA risk score may have a lower estimated coronary heart disease risk in Thai patients, especially in patients with multiple risk factors for coronary heart disease. Diabetes mellitus was the strongest predictor of high CAC.

Keywords: Thai cardiovascular risk score, Multi-Ethnic Study of Atherosclerosis (MESA), Coronary artery calcium (CAC), Predictor, Correlation, Coronary heart disease (CHD)

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ความสัมพันธ์ระหว่างการทำนายความเสี่ยงต่อการเกิดโรคหลอดเลือดหัวใจโดยใช้คะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทยและคะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจจากการศึกษา MESA ในผู้ป่วยไทย

กุลธัช ชอบใช้ พบ. ว.ว. อายุรศาสตร์ [1] **ชัยศิริ วรรณลภากร พบ. ว.ว. อายุรศาสตร์, ว.ว. โรคหัวใจ**[2]
ศุวรา อิสรไกรศีล พบ. ว.ว. รังสีวิทยาวินิจฉัย[3] **ธีธัช อนันต์วัฒนสุข พบ. ว.ว. อายุรศาสตร์, ว.ว. โรคหัวใจ**[1]
เผดิมวุฒิ ธีระวงศ์สกุล พบ. ว.ว. อายุรศาสตร์, ว.ว. โรคหัวใจ[1*]

[1] หน่วยโรคหัวใจ ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย
[2] ศูนย์โรคหัวใจ ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กรุงเทพมหานคร ประเทศไทย
[3] ภาควิชารังสีวิทยา คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย
* ผู้ติดต่อ, อีเมล: padoemwut@nmu.ac.th
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บทคัดย่อ

วัตถุประสงค์: จุดประสงค์ของการศึกษาเพื่อประเมินความสัมพันธ์ระหว่างคะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทย (Thai cardiovascular risk score) เทียบกับคะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของผู้ป่วยจากการศึกษา MESA (the Multi-Ethnic Study of Atherosclerosis) และหาปัจจัยเพื่อพยากรณ์กลุ่มผู้ป่วยคะแนนแคลเซียมในหลอดเลือดหัวใจสูงในผู้ป่วยไทยซึ่งไม่มีประวัติโรคหลอดเลือดหัวใจ

วิธีดำเนินการวิจัย: การศึกษานี้เป็นการศึกษาแบบตามขวาง ประเมินอาสาสมัครที่ไม่เคยได้รับการวินิจฉัยว่าเป็นโรคหลอดเลือดแดงแข็ง และได้รับการตรวจภาพรังสีคอมพิวเตอร์ของหน้าอก ในคณะแพทยศาสตร์วชิรพยาบาล ตั้งแต่ 1 กรกฎาคม 2561 ถึง 31 ธันวาคม 2561 วิเคราะห์คะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทย, คะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจของผู้ป่วยหลายเชื้อชาติจากการศึกษา MESA และ คะแนนแคลเซียมในหลอดเลือดหัวใจ วิเคราะห์ปัจจัยเสี่ยงของการมีคะแนนแคลเซียมในหลอดเลือดหัวใจสูงด้วยการวิเคราะห์ข้อมูลแบบตัวแปรเดียว และแบบหลายตัวแปร

ผลการวิจัย: กลุ่มอาสาสมัครจำนวน 84 คน (อายุเฉลี่ย 55.1 ปี และเพศหญิงร้อยละ 65.5) ส่วนใหญ่คะแนนแคลเซียมของหลอดเลือดหัวใจเท่ากับศูนย์ (46.4%) เมื่อเทียบคะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทยกับคะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจจากการศึกษา MESA พบว่ามีความสัมพันธ์ระดับสูง และความสัมพันธ์สูงกว่า เมื่อเทียบคะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจจากการศึกษา FHS กับการศึกษา MESA (ค่า r เท่ากับ 0.818: $p < 0.001$ และ ค่า r เท่ากับ 0.747; $p < 0.001$ ตามลำดับ) โดยยอมรับความแตกต่างเฉลี่ยเท่ากับ -0.73, ส่วนเบี่ยงเบนมาตรฐานเท่ากับ 0.242 และ ความแตกต่างเฉลี่ยเท่ากับ -3.78, ส่วนเบี่ยงเบนมาตรฐานเท่ากับ 0.539 ตามลำดับ) จากการวิเคราะห์ปัจจัยเสี่ยงแบบหลายตัวแปรพบว่าเบาหวาน (OR: 28.39, 95% CI:1.92-420.09; $p = 0.015$) และอายุมากกว่า 60 ปี (OR: 38.26, 95% CI:13.76-389.49; $p = 0.002$) เป็นปัจจัยเสี่ยงอิสระในการพยากรณ์คะแนนแคลเซียมของหลอดเลือดหัวใจระดับสูง

สรุป: คะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทย และคะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจจากการศึกษา MESA มีความสัมพันธ์กันระดับสูงในการทำนายความเสี่ยงต่อการเกิดโรคหลอดเลือดหัวใจในประชากรไทย แต่คะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจจากการศึกษา MESA อาจจะต่ำกว่าโดยเฉพาะอย่างยิ่งผู้ป่วยที่มีหลายปัจจัยเสี่ยงของโรคหลอดเลือดหัวใจ เบาหวานเป็นปัจจัยพยากรณ์คะแนนแคลเซียมของหลอดเลือดหัวใจเกี่ยวข้องมากที่สุด

คำสำคัญ: คะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทย, คะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจจากการศึกษา MESA, คะแนนแคลเซียมของหลอดเลือดหัวใจ, การทำนาย, โรคหลอดเลือดหัวใจ

วันที่รับบทความ 4 มีนาคม 2564 **วันแก้ไขบทความ** 8 เมษายน 2565 **วันตอบรับบทความ** 22 เมษายน 2565

Introduction

Coronary heart disease (CHD) is a major global problem and cause of morbidity and mortality worldwide. Despite a reduction in mortality rates in recent decades, coronary artery disease is still responsible major leading cause of death in Thailand and developing countries. Early diagnosis of asymptomatic adults by identifying and controlling known and established cardiovascular risk factors should be made to reduce cardiovascular morbidity and mortality. Great efforts are invested in primary prevention and the asymptomatic population which is classed as low-risk, intermediate-risk, and high-risk for appropriate risk modification. The high-risk population will gain more benefits from intensive risk control than the low-risk population. However, there are several available risk scores. The Framingham risk score (FRS) is also one of the most well-known models to estimate the 10-year cardiovascular risk of an individual and stratify cardiovascular risk in the United States[1]. However, some populations, such as intermediate-risk, could not use the Framingham risk score to predict risks accurately[2]. Coronary artery calcium is a better indicator of coronary heart disease risk factor prediction than the Framingham risk score (FRS). These findings suggest that the coronary artery calcium combined with FRS makes it possible to predict the occurrence of CHD better and allows for effective risk prevention[3]. Thus, other tests such as coronary artery calcium scoring combined with the Framingham risk score in asymptomatic adults may provide prognostic information better than either method alone.

Coronary calcium quantified by computed tomography (CT) is a specific marker of coronary atherosclerosis. The risk factors associated with coronary calcification are age, sex hypertension, diabetes, dyslipidemia, and smoking[3]. The coronary artery calcium (CAC) score was developed by the determination of the volume of calcium and mass calcium score with the Agatston method[4-6]. The coronary artery calcium score ≥ 80 Hounsfield units (HU) had 74% specificity and 89% sensitivity to predict the risk of acute coronary syndrome and mortality within 3.6 years. From the Multi-Ethnic Study of Atherosclerosis (MESA), The CAC score combined with established traditional risk factors from the Framingham heart study showed significant improvement in the risk stratification to predict coronary heart disease[3, 5-12]. For the net reclassification improvement (NRI) in the intermediate-risk persons, 16% were reclassified to high risk, while 39% were reclassified to low risk[9]. In the very low-risk persons, the probability of identifying persons with clinically significant levels of coronary artery calcium is low but becomes greater in low and intermediate-risk persons[7].

Thai cardiovascular risk score (TCVRS), based on an EGAT study[15], was used to estimate the 10-year risk for atherosclerotic cardiovascular disease in the Thai population without previous atherosclerotic cardiovascular disease. This estimator could be used without blood testing, required waist circumference and height, or use with blood testing.

This study determines the correlation between Thai cardiovascular risk score (TCVRS) and Multi-Ethnic Study of Atherosclerosis (MESA) risk score in Thai people without a history of atherosclerotic cardiovascular disease.

Method

Study design

A cross-sectional cohort study determines the correlation between Thai cardiovascular risk score (TCVRS) and 10-year risk of coronary heart disease using the MESA risk score in Thai populations. This study was conducted at Vajira Hospital from July to December 2018.

All patients scheduled to evaluate chest computed tomography scans were selected and eligible for inclusion criteria will be assessed to measure coronary artery calcification with ECG-gated cardiac computed tomography (CT). An unenhanced low-dose CT scan by Philips Ingenuity 128-slide CT scanner is routinely performed

in patients undergoing cardiac CT for coronary calcium score. After CT scans, the post-processing data will be analyzed using the HeartBeat–CS software application. Agatston score is a semi-automated tool to calculate a score based on the extent of coronary artery calcification detected by CT scanning, finally interpreted data by the radiologist.

Baseline characteristics (age, sex, body weight, body mass index, history of smoking, current medications, underlying disease, vital signs, and laboratory data), TCVRS estimator, the MESA: 10-year coronary heart disease estimator, and coronary artery calcium score were analyzed.

All participants had provided written informed consent. Study protocols were approved by the institutional review board at Navamindradhiraj University.

Study population and endpoints

The eligibility of candidate patients was based on the following criteria: 1) adult patients aged > 18 years; 2) scheduled to evaluate computed tomography scan with contrast from July to December 2018; 3) patients who have agreed to undergo a computerized coronary artery calcium scan.

The exclusion criteria were: 1) established atherosclerotic diseases (ischemic stroke, ischemic heart disease, carotid artery stenosis, and peripheral arterial disease); 2) tachycardia (heart rate > 100 bpm); 3) pregnancy or breastfeeding; 4) immunocompromised patients (inherited and acquired immunocompromised diseases, including HIV patients, neutropenia, bone marrow, and organ transplantation); 5) solid and hematologic malignancies.

Definition

The TCVRS categories:

- Low risk (< 10%), intermediate risk (10 to < 20%), high risk (≥ 20%)

The FRS categories according to ASCVD risk:

- Low risk (< 7.5%), intermediate risk (7.5 to < 20%), high risk (≥ 20%)

The coronary artery calcium score categories:[9]

- Zero (0), low (1-100), intermediate (101-300), and high (>300)

The primary endpoint was a correlation between Thai cardiovascular risk score and Multi-Ethnic Study of Atherosclerosis risk score in Thai adults without a history of atherosclerotic cardiovascular disease. The secondary endpoints included predictive factors for high CAC and the correlation between the Thai cardiovascular risk score and The Framingham risk score.

Statistical analysis

The data were analyzed using the STATA software, version 13. Discrete variables were presented as percentages for categorical variables and means with standard deviations for the continuous variable. Univariate and multivariate logistic regression models evaluated the risk factors associated with high coronary calcium scores. The correlation was analyzed by Pearson correlation and Bland-Altman plot to determine the association between Thai cardiovascular risk score and 10-year risk of coronary heart disease using the MESA score combined with a coronary artery calcium score. P-values of less than 0.05 were statistical significance.

Results

Baseline characteristics

We identified 84 chest computed tomography scans performed in adults without established atherosclerotic diseases. The participants included in the analysis mainly were female (65.5%), and the mean age was 55.1±15.8 years. Patients were previously diagnosed with hypertension (39.3%), dyslipidemia (34.5%), diabetes mellitus (11.9%), and 9.5% were current smokers. All the characteristics of the participants included in the study are detailed in Table1.

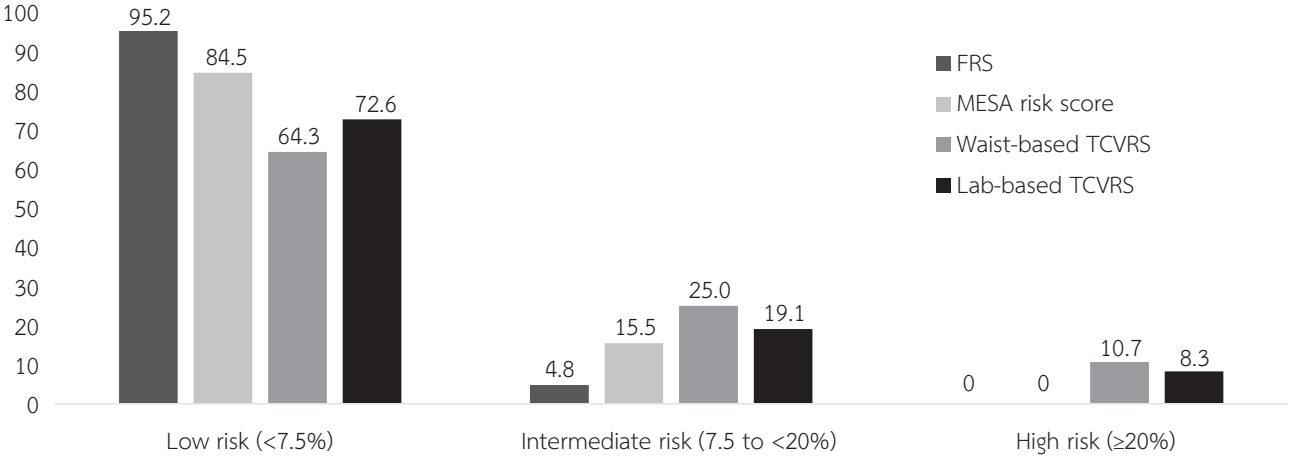
Table 1:

Baseline characteristics of study participants

Demographics	All participants (n = 84)	CAC score		P-value*
		0 (n = 39)	> 0 (n =45)	
Female	55 (65.5%)	28 (71.8%)	27 (60.0%)	0.257
Age (year), mean (SD)	55.1±15.8	46.1±15.0	63.2±11.5	0.128
Family history of CHD	3 (3.6%)	1 (2.6%)	2 (4.4%)	0.643
BMI (kg/m^2), mean (SD)	22.4±4.2	22.1±4.0	24.5±10.8	0.501
Current smoker	8 (9.5%)	1 (2.6%)	7 (15.6%)	0.051
Underlying disease				
Hypertension	33 (39.3%)	7 (17.9%)	26 (57.8%)	<0.001
Dyslipidemia	29 (34.5%)	10 (25.6%)	19 (42.2%)	0.111
Diabetes mellitus	10 (11.9%)	1 (2.6%)	9 (20.0%)	0.014
Medications				
HMG-CoA reductase inhibitor	23 (27.4%)	7 (17.9%)	16 (35.5%)	0.071
Antiplatelets	10 (11.9%)	2 (5.1%)	8 (17.8%)	0.074
Beta-blockers	11 (13.1%)	1 (2.6%)	10 (22.2%)	0.008
ACEIs or ARBs	15 (17.9%)	4 (10.3%)	11 (24.4%)	0.090
Calcium antagonists	16 (19.0%)	3 (7.7%)	13 (28.9%)	0.014
Diuretics	7 (8.3%)	0 (0.0%)	7 (15.6%)	0.010
Systolic blood pressure (mmHg)	126.7±14.6	124.0±13.0	129±16.0	0.175
Diastolic blood pressure (mmHg)	74.3±10.2	72.8±8.4	76±12.0	0.580
Laboratory investigation				
Total Cholesterol (mg/dl), mean (SD)	200.6±38.7	200.9±42.2	200.4±35.7	0.242
LDL Cholesterol (mg/dl), mean (SD)	118.4±34.9	122.5±43.0	115.6±28.4	0.214
HDL Cholesterol (mg/dl), mean (SD)	61.5±14.6	62.2±15.0	60.9±14.6	0.257
Triglyceride (mg/dl), mean (SD)	101.5±41.3	101.3±45.0	101.7±39.1	0.248
HbA1C (mg/dl), mean (SD)	5.9±0.6	5.7±0.4	7.43±9.3	0.009
BUN (mg/dl), mean (SD)	13.6±4.2	13.2±3.8	14±4.4	0.763
Creatinine (mg/dl), mean (SD)	0.8±0.3	0.7±0.4	0.8±0.4	0.332

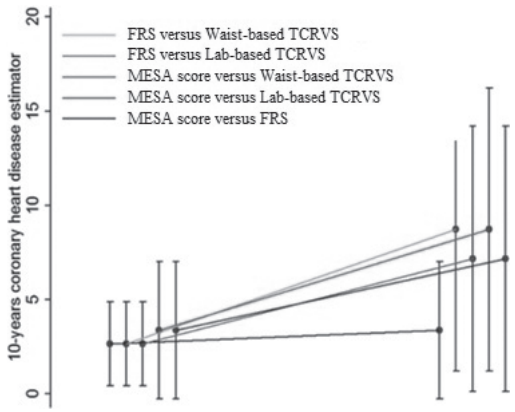
Most participants had a likely low risk for coronary heart diseases. During the study period, no participants had cardiovascular events. The coronary artery calcium score was calculated in all 84 participants and showed that patients had 39 (46.4%) in zero CAC, 26 (31.0%) in low, 9 (10.7%) in intermediate, and 10 (11.9%) in high CAC. Based on the Framingham risk score assessment alone, the patients were 80 (95.2%) in low-risk, 4 (4.8%) in intermediate-risk, and no high-risk patients. Following the MESA risk score using FRS with CAC score, 10 of 80 (12.5%) low-risk patients in FRS were reclassified as intermediate-risk, while 1 of 4 (25.0%) of the intermediate-risk patients were reclassified as low-risk patients, as illustrated in Figure 1. According to the laboratory-based Thai cardiovascular risk score (TCVRS), 54 of 84 participants were classified as low risk, 21 of 84 (25.0%) as intermediate risk, and 9 of 84 (10.7%) as high risk.

The FRS and MESA risk scores assessment tends to have a lower risk estimation than the Thai cardiovascular risk score (TCVRS) in the Thai people, as illustrated in Figure 2. According to the comparison of lab-based TCVRS and MESA risk scores comparison, 10 of 71 (14.1%) participants in the low-risk group of MESA risk score were reclassified as a high-risk and intermediate-risk group of lab-based TCVRS, 1 of 71 (1.4%) participant in the low-risk group of MESA risk score was reclassified as a high-risk group, and 9 of 71 (12.7%) participants in low-risk group of MESA risk score was reclassified as an immediate-risk group of lab-based TCVRS respectively. 6 of 13 (46.2%) participants in the intermediate-risk group of the MESA risk score were reclassified as high risk of lab-based TCVRS.



Abbreviations: FHS, Framingham risk score; MESA risk score, the Multi-Ethnic Study of Atherosclerosis risk score; TCVRS, Thai cardiovascular risk score.
MESA categories according to ASCVD risk: risk (< 7.5 %), Intermediate risk (7.5 to <20%), High risk (≥20%)
TCVRS categories: Low risk (< 10 %), Intermediate risk (10 to <20%), High risk (≥20%)

Figure 1: Coronary heart disease risk categories by using the Framingham risk score, MESA risk score, and Thai cardiovascular risk score



Abbreviations: FHS, Framingham risk score; MESA, the Multi-Ethnic Study of Atherosclerosis risk score; TCVRS, Thai cardiovascular risk score

Figure 2: Trend of coronary heart disease estimated risk in each estimator

The correlation between various risk assessment methods was performed by Pearson's correlation. The FRS and MESA risk score were strongly correlated ($r = 0.818$; $p < 0.001$). The agreement between both risk estimators was plotted by Bland& Altman and seems to be good as well, with a mean difference = -0.73 and SD = 0.242. The correlation and agreement are shown in Figure 3.

The correlation between the lab-based TCVRS and MESA risk score were strong correlation ($r = 0.747$; $p< 0.001$). The agreement was good as well with mean difference = -3.78 and SD = 0.539.

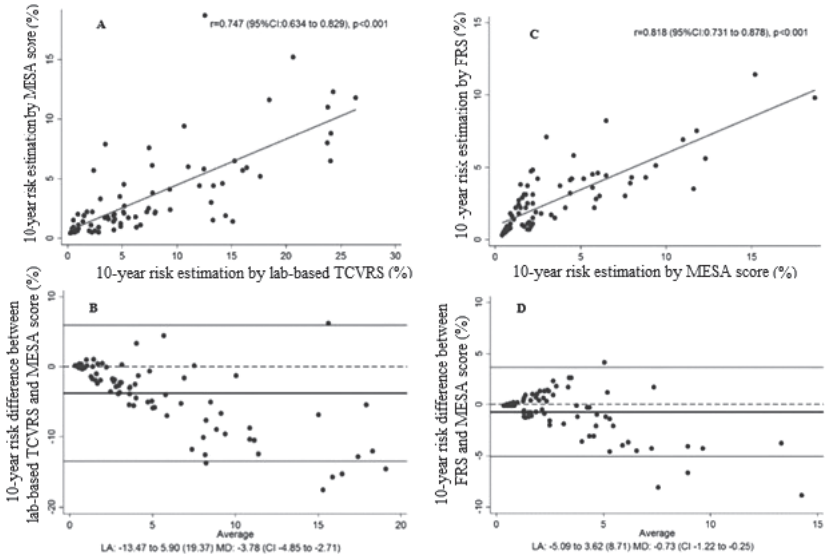
According to this data, although TCVRS had a strong correlation and agreement with FRS and MESA risk scores, but seems to be that the MESA risk score may have a lower estimated CHD risk in patients, especially in patients with multiple risk factors for coronary heart disease.

In the univariate analysis, diabetes mellitus was the strongest factor to predict high CAC (OR 17.50, 95% CI: 3.5-86.5, $p < 0.001$). The age ≥ 60 years (OR 13.4, 95% CI: 1.6-113.1, p=0.017) and level of glycosylated hemoglobin ≥ 6.5 (OR 5.8, 95%CI: 1.14-29.0, p=0.034) were also risk factors to predict high CAC.

Multivariate logistic regression analysis was performed to determine the independent predictive factors related to high CAC and showed diabetic mellitus and age ≥ 60 years were independent predictive factors for high CAC (Table 2).

Discussion

According to 2018 AHA guidelines on the management of blood cholesterol, primary intervention in intermediate-risk patients should initiate active physical activity, change in lifestyle, and combined with a moderate-intensity statin to reduce coronary heart disease risk. Otherwise, high-risk patients may have to use more intensive therapy strategies. The MESA risk score was developed to predict a 10-year CHD risk score accurately by adding the CAC score. Although the MESA study enrolls patients from various ethnic backgrounds, Asians account for 12% of the total. The external validity of the general population will be questioned, particularly among the Thai people[3]. The Thai cardiovascular risk score is another developed clinical risk assessment tool for the Thai people based on an EGAT study[15]. Our study evaluates the MESA risk score, which was developed by combining FRS and CAC scores to reclassify the risk of coronary heart disease and determine the correlation between the MESA risk score and TCVRS.



A- Linear regression analysis and Pearson's coefficient between lab-based TCVRS and MESA risk score,
B- Bland-Altman agreement between lab-based TCVRS and MESA risk score,
C- Linear regression analysis and Pearson's coefficient Correlation between FRS and MESA risk score,
D- Bland-Altman agreement Correlation between FRS and MESA risk score
Abbreviations: FHS, Framingham risk score; MESA, the Multi-Ethnic Study of Atherosclerosis risk score; Lab-based TCVRS, Laboratory-based Thai cardiovascular risk score; r = Pearson's coefficient of correlation

Figure 3: Correlation between lab-based TCVRS and MESA risk score

Table 2:
Univariable and Multivariable predictors of coronary artery calcium

Variables	Univariable analysis			Multivariable analysis		
	OR[1]	95% CI	p-value	Adjusted OR[2]	95% CI	p-value
Age ≥ 60 (years)	13.4	1.6-113.1	0.017	28.39	1.9-420.1	0.015
Female	2.0	0.4-10.2	0.418			
FH of CHD	4.6	0.4-56.1	0.236			
BMI ≥ 23 (kg/m 2)	0.8	0.2-3.6	0.814			
Diabetes mellitus	17.5	3.5-86.5	<0.001	38.26	3.8-389.5	0.002
Hypertension	2.1	0.5-8.5	0.298			
Dyslipidemia	2.7	0.7-10.8	0.172			
Current smoker	0.4	0.1-3.7	0.437			
HMG-CoA reductase inhibitor	2.4	0.6-9.7	0.234			
Antiplatelets	2.4	0.4-13.6	0.324			

Table 2:

Univariable and Multivariable predictors of coronary artery calcium (Continued)

Variables	Univariable analysis			Multivariable analysis		
	OR[1]	95% CI	p-value	Adjusted OR[2]	95% CI	p-value
Beta-blockers	4.2	0.9-20.1	0.073			
ACEIs or ARBs	2.6	0.6-12.0	0.212			
Calcium antagonists	2.4	0.5-10.8	0.259			
Diuretics	1.4	0.2-13.5	0.751			
Blood pressure > 140/90 mmHg	2.2	0.5-9.8	0.310			
Total Cholesterol ≥ 200 mg/dl	1.3	0.3-5.2	0.725			
HDL Cholesterol < 50 mg/dl	1.3	0.2-6.7	0.798			
Triglyceride ≥ 150 mg/dl	2.1	0.4-11.7	0.399			
HbA1C ≥ 6.5%	5.8	1.1-29.0	0.034			

Abbreviations: OR, Odds Ratio; CI, confidence interval

[1]Crude Odds Ratio estimated by Binary logistic regression analysis.

[2]Adjusted Odds Ratio calculated by Multiple logistic regression analysis (backward stepwise method) adjusted for age and diabetes mellitus.

The principal findings of the study were the following. First, the intermediate-risk group is the most interesting group for risk reclassification. The MESA study showed that the MESA risk score could reclassify the intermediate-risk group into low and high-risk groups. 39% of participants in the intermediate-risk group were reclassified as low risk and 16% as high risk. However, our research found that the MESA risk score reclassified 25% of the intermediate-risk group as low risk but not high risk. As a result, the main participants in the cohort were low risk than in the MESA study and the lifestyles of Thai people are different from western people[5]. Our study also demonstrated that 12.5% of low-risk participants were reclassified as an immediate risk but not as high risk. Second, the correlation between the MESA risk score and the laboratory-based TCVRS was stronger than the correlation between the FRS and MESA risk scores. Increased CHD risk predicted by TCVRS was almost certainly associated with a more significant mean difference than low risk. The waist circumference-based and laboratory-based Thai CV risk scores were classified as high-risk at 10.7% and 8.3% of total participants, respectively, but no high-risk patients were identified using FRS or MESA risk scores. According to this data, it seems to be that MESA risk scores may have a lower estimated CHD risk than TCVRS in Thai people, especially patients with multiple risk factors for coronary heart disease. Finally, age, gender, hypertension, diabetes, dyslipidemia, and smoking were all independent predictors of high CAC in a previous report. This study showed that only aged ≥60 years and diabetes mellitus were significantly associated with high CAC.

According to the study finding, MESA risk scores and FRS in Thai people may have underestimated cardiovascular risk in the Thai population. The Thai cardiovascular risk scores may be the most appropriate method for coronary heart disease risk estimation in Thai people.

Limitations

This study has several limitations. First, we included a small population for analysis because many patients met exclusion criteria and had a short study period. Second, patients had no

cardiovascular events. Therefore, both specificity and sensitivity were not evaluated.

Conclusions

There is a strong correlation between TCVRS and MESA score in Thai populations, but the MESA score may be lower estimated CHD risk in Thai patients, especially in patients with multiple risk factors for coronary heart disease. Diabetes mellitus was the strongest predictor of high CAC.

Acknowledgements

The authors would like to thank the staff of the Radiology Division, Vajira hospital, for coronary artery calcium data retrieval. This study was supported by the Navamindradhiraj University research fund.

Potential conflicts of interest

The authors declare no conflict of interest.

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Risk Factors of Blood Transfusion in Knee Arthroplasty

Pruk Chaiyakit MD[1]
Weeranate Umpanpong MD[1]
Tawipat Watcharotayangkoon MD[1*]

[1] Orthopedics Department, Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand
* Corresponding author, e-mail address: tawipat@nmu.ac.th
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Abstract

Background: The amount of blood transfusion after knee arthroplasty seem to vary in different reported study. We carried out a retrospective study to analysis pre-operative risk factors for blood transfusion in patient who underwent knee arthroplasty in our institution.

Methods: A retrospective study of 190 patients treated with 194 procedure (186 unilateral knee arthroplasty, 4 bilateral knee arthroplasty) from November 2014 to October 2015 was analyzed. A univariate analysis was performed to establish the relationship between all variables and the need for postoperative transfusion. Variables that were determined to have significant relationship were included in a multivariable analysis.

Results: The univariate analysis revealed a significant relationship between need for postoperative blood transfusion and preoperative hemoglobin levels, surgical technique, arthrotomy approach, DVT prophylaxis, surgical technique and surgeon experience. The multivariate analysis identified a significant relationship between need for transfusion and preoperative hemoglobin level and surgical technique. Patients with a preoperative hemoglobin less than 12 g/dL had a 5.1 times greater risk of having a transfusion than those with a hemoglobin level ≥ 12 g/dL. The surgical technique with computer assisted surgery had a 0.15 times lesser risk of having a transfusion than those with the conventional technique.

Conclusion: The preoperative hemoglobin level < 12 g/dL was shown to increase risk of the need for blood transfusion after knee arthroplasty, while computer assist surgery total knee arthroplasty was shown to decrease risk of blood transfusion. We suggested that patients with preoperative hemoglobin < 12 g/dL need to be crossmatching PRC in pre-operative steps.

Keywords: blood transfusion, transfusion, total knee arthroplasty, total knee replacement, TKA

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ปัจจัยเสี่ยงต่อการให้เลือดทดแทนในผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียม

พฤกษ์ ไชยกิจ พ.บ. วว.ศัลยศาสตร์ออร์โธปิดิกส์[1]
วีรเนตร อำพันพงษ์ พ.บ.[1]
ทวิพัฒน์ วัชโรทยางกูร พ.บ.[1*]

[1] ภาควิชาออร์โธปิดิกส์ คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช กรุงเทพมหานคร ประเทศไทย

* ผู้ติดต่อ, อีเมล: tawipat@nmu.ac.th

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บทคัดย่อ

วัตถุประสงค์: ปริมาณการให้เลือดหลังการผ่าตัดเปลี่ยนข้อเข่าเทียมมีจำนวนที่แตกต่างกันในแต่ละงานวิจัย ทางทีมผู้วิจัยจึงทำการวิจัยนี้ขึ้นมาเพื่อศึกษาว่าปัจจัยใดบ้างที่ส่งผลต่อการได้รับเลือดหลังการผ่าตัดเปลี่ยนข้อเข่าเทียม ซึ่งจะนำผลที่ได้ไปใช้ในการเตรียมผู้ป่วยก่อนผ่าตัด ซึ่งจะเป็นการช่วยลดค่าใช้จ่าย ระยะเวลา และลดปริมาณการเตรียมเลือดในผู้ป่วยกลุ่มที่ไม่มีความจำเป็นในการได้รับเลือดหลังการผ่าตัดเปลี่ยนข้อเข่าเทียม

วิธีดำเนินการวิจัย: ศึกษาแบบข้อมูลแบบย้อนหลัง ในผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียม ที่โรงพยาบาลวชิรพยาบาล ตั้งแต่ช่วง พฤศจิกายน พ.ศ.2557 ถึง ตุลาคม 2558 จำนวน 190 ราย โดยบันทึกปัจจัยที่อาจส่งผลต่อการได้รับเลือดของผู้ป่วยในสมมติฐาน เก็บข้อมูลผู้ป่วยจากฐานข้อมูลคอมพิวเตอร์ และแฟ้มเวชระเบียนผู้ป่วย นำข้อมูลมาวิเคราะห์หาความสัมพันธ์โดยใช้สถิติการวิเคราะห์ความถดถอยพหุโลจิสติก พหุกลุ่ม (multiple logistic regression analysis)

ผลการวิจัย: การวิเคราะห์ปัจจัยที่ส่งผลต่อการให้เลือดทดแทนในผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมโดยใช้สถิติการวิเคราะห์ความถดถอยพหุโลจิสติกแบบ univariable analysis พบว่าปัจจัยที่ส่งผลต่อการให้เลือด ทดแทนในผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าอย่างมีนัยสำคัญทางสถิติ ได้แก่ ระดับฮีโมโกลบินก่อนผ่าตัด เทคนิคการผ่าตัด วิธีการเปิดผิวข้อ ระยะเวลาการผ่าตัด และประสบการณ์ของแพทย์ผู้ผ่าตัด แต่เมื่อนำปัจจัยเหล่านี้มาวิเคราะห์แบบความถดถอยพหุโลจิสติก พหุกลุ่มและควบคุมอิทธิพลของปัจจัยกวน พบว่า ผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมที่มีระดับฮีโมโกลบินก่อนผ่าตัดน้อยกว่า 12 กรัมต่อเดซิลิตร จะมีโอกาสได้รับการให้เลือดทดแทนมากกว่ากลุ่มผู้ป่วยที่มีระดับฮีโมโกลบินก่อนผ่าตัดมากกว่าหรือเท่ากับ 12 กรัมต่อเดซิลิตรเป็น 5.10 เท่า ผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมด้วยเทคนิคใช้คอมพิวเตอร์ช่วยผ่าตัดจะมีโอกาสได้รับการให้เลือดทดแทนน้อยกว่ากลุ่มผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียมด้วยเทคนิค มาตรฐานเป็น 0.15 เท่า

สรุป: ปัจจัยที่เพิ่มโอกาสได้รับเลือดหลังการผ่าตัดเปลี่ยนข้อเข่าเทียมคือ ผู้ป่วยที่มีค่าฮีโมโกลบินก่อนผ่าตัดน้อยกว่า 12 กรัมต่อเดซิลิตร และปัจจัยที่ช่วยลดโอกาสในการได้รับเลือดหลังผ่าตัดเปลี่ยนข้อเข่าเทียม คือการผ่าตัดเปลี่ยนข้อเข่าเทียมโดยใช้คอมพิวเตอร์ช่วยผ่าตัด

คำสำคัญ: การให้เลือด, การผ่าตัดเปลี่ยนข้อเข่าเทียม, ข้อเข่าเทียม

วันที่รับบทความ 21 ตุลาคม 2563 **วันแก้ไขบทความ** 21 มิถุนายน 2564 **วันตอบรับบทความ** 20 มกราคม 2565

Introduction

In current treatment of osteoarthritis (OA) of knee joint, total knee arthroplasty (TKA) are more popular than the past, due to high success rate and improvement of functional outcomes. However, amount of blood loss in unilateral TKA can up to 2,000 ml and 3,000 ml in bilateral TKA[1], that makes incidence of blood transfusion after TKA around the world is 4-46% or 15 million times per year[2].

The percentage of blood transfusion in TKA patients was 20% in our hospital. In preoperative preparation guideline of Vajira Hospital, we have to prepare pack red cell (PRC) for all patients. Statistic showed that in 80% of patients, the PRC was unnecessary and make more cost and more task for the nurses and blood bank officer.(reference)

Larocque, et al. reported that preoperative hemoglobin (Hb) level, type of arthroplasty, revision surgery, autologous donor status and patient weight are the risk factors for blood transfusion[3].

Jose A. Salido, et al. reported that preoperative Hb level < 13 g/dL increased 4-fold risk for blood transfusion than Hb 13-15 g/dL and increased 15-fold risk than Hb > 15 g/dL group[4].

Sara Moráis, et al. reported that preoperative Hb < 12 g/dl, ASA status III and nonobese BMI patients are risk factor for blood transfusion[5]. Whereas, there was no study about surgical technique, surgical approach, used of computer assist surgery and prosthetic type of TKA, that can be the factor of blood transfusion.

So we carried out this retrospective study for analyze the pre-operative risk factors of blood transfusion after TKA. If the risk factors were found, we will used it for revise pre-operative preparation guideline to be cross matching PRC only patient that have a risk factor, and this will reduce step for patient, cost and task for the officer in Vajira Hospital.

Methods

A retrospective analysis was conducted on data from inpatient medical record and Vajira Hospital database of 190 patients who underwent TKA at Orthopedic Department, Vajira Hospital between November 2014 to October 2015.

We include all patient who diagnosed primary or secondary OA knee, which failed in conservative treatment more than 6 months, indicated for unilateral or bilateral TKA, available preoperative Hb measured, and American Society of Anesthesiology categories I-III. We have no exclusion criterion in this study.

Data in this study was obtained from outpatient/inpatient medical record file and Vajira Hospital computer database of all patients who included in the study. Data that be the variable study were age, gender, weight, BMI, underlying diseases, ASA classification, diagnosis (primary, secondary), knee side, pre-operative Hb level(g/dl), type of anesthesia, surgical technique (conventional, computer assisted surgery, minimal invasive surgery), arthrotomy approach, tranexamic acid usage, initial intra-operative blood pressure, operative time, drainage used, post-operative VTE prophylaxis and surgeon experience.

All procedure were performed by orthopedists at Vajira Hospital. Surgeon who perform TKA more than 50 cases per year define as experienced surgeon. All patients were received same routine post-operative protocol and physical therapy TKA program of Vajira Hospital. Blood hemoglobin levels were obtained at ward after operation 4 hrs. and post-operative day 1. There was no criteria for blood transfusion in the period of data collected.

All statistical analysis were performed using SPSS Version 23. Patient demographic data using means and standard deviation. The relationship between blood transfusion with various variables were analyzed by chi-square test and fisher's exact test. The variables that related to blood transfusion were analyzed by multiple logistic regression analysis, and the variables that found to be insignificant in univariate analysis were excluded from the multivariable analysis. A P-value of < 0.05 was considered statistically significant for associated variables.

Result

A total of 190 patients were include in this study, 160 (84.2%) were females and 30 (15.6%) were males. Most of patients were in 60-69 years age group and BMI was in pre-obesity group (mean 27.09 +/-3.99 kg/m2). Patients with diagnosis of osteoarthritis right (Rt.) knee were 93, equal to left (Lt.) side and 4 were bilateral, mostly were primary osteoarthritis [181(95.3%)], secondary OA from inflamatory joint disease were 3(1.6%) and 6(.....%) were revision cases. Patients with pre-operative Hb < 12 g/dl were 58 equals to 12-13 g/dl and 74 were >13 g/dl. Every patient undergone TKA with regional anesthesia and tourniquet used before incision. Arthrotomy approach, 180(94.7%) patients were midvastus and 10 were medial parapatellar. Surgical technique, 78 patients were use conventional technique, 72 patients were used computer assist surgery (CAS) and 40 were used minimal invasive technique. Other demographic data of patients were show in table 1.

Table 1:
Characteristics of patients (n=190)

Variables	n	(%) ?
Age		
40-49	1	(0.5)
50-59	34	(17.9)
60-69	78	(41.1)
70-79	68	(35.8)
≥ 80	9	(4.7)
Gender		
Male	30	(15.8)
Female	160	(84.2)
Weight	65.50 ± 11.17	
BMI	27.09 ± 3.99	
Normal / pre-obesity (18.5-30)	144	(75.8)
Class I-II (30-40)	46	(24.2)
Underlying disease		
Hypertension	154	(81.1)
Diabetes mellitus	45	(23.7)
Dyslipidemia	87	(45.8)
Cardiomyopathy	19	(10.0)
Other Underlying disease	18	(9.5)
Knee side		
Right	93	(48.9)
Left	93	(48.9)
Both	4	(2.1)

Table 1:
Characteristics of patients (n=190) (Continued)

Variables	n	(%) ?
ASA Classification		
ASA Class I	12	(6.3)
ASA class II	157	(82.6)
ASA class III	21	(11.1)
Pre-operative Hb level (g/dl)	12.60 ± 1.22	
< 12	58	(30.5)
12-13	58	(30.5)
> 13	74	(38.9)
Surgical Technique		
Conventional	78	(41.1)
Computer assist surgery	72	(37.9)
Minimal invasive surgery	40	(21.1)
Arthrotomy approach		
Mid vastus	180	(94.7)
Medial parapatella	10	(5.3)
Tranexamic acid		
use	163	(85.8)
nonuse	27	(14.2)
Intra-operative systolic blood pressure (Initial)		
101-120 mmHg	18	(9.5)
121-140 mmHg	75	(39.5)
141-160 mmHg	81	(42.6)
161-180 mmHg	16	(8.4)

Table 1:
Characteristics of patients (n=190) (Continued)

Variables	n	(%) ?
Postoperative DVT prophylaxis		
No use	67	(35.3)
ASA	31	(16.3)
Apixaban	49	(25.8)
Dabigatran	43	(22.6)
Preoperative diagnosis		
Primary OA	181	(95.3)
Inflammatory OA	3	(1.6)
Revision TKA	6	(3.2)
Operative time		
< 1 Hour	20	(10.5)
1-2 Hours	161	(84.7)
2-3 Hours	9	(4.7)
Surgeon experience		
Yes	151	(79.5)
No	39	(20.5)
Use of drainage		
Yes	186	(97.9)
No	4	(2.1)
Blood transfusion		
No	140	(73.7)
Yes	50	(26.3)
1 unit	31	(16.3)
2 unit	19	(10.0)

Data are presented as n (%) or mean ± SD

We found that 50 (26.3%) of patients were need for blood transfusion (table 1). Analysis of the factors affecting blood transfusion was done using chi-square tests or fisher's exact tests, found that factors related to blood transfusion with statistically significant mostly was preoperative Hb level, follow by surgical techniques, arthrotomy approach, and surgeon experience respectively (Table 2).

Likewise, univariate logistic regression analysis found that factors related to blood transfusion after TKA with statistically significant were preoperative Hb < 12 g/dl (OR= 6.83, 95%CI: 3.36-13.87), CAS techniques (OR= 0.24, 95%CI: 0.11-0.56), medial parapatella approach (OR= 7.43, 95%CI: 1.84-30.00), operative time > 1 hr. (OR= 7.96, 95%CI: 1.00-59.06), post-operative VTE prophylaxis with Dabigatran (OR= 0.37, 95%CI: 0.14-0.97) and inexperienced surgeon (OR= 2.76, 95%CI: 1.32-5.80) (Table 3).

After control the influence of confounding factors and multiple logistic regression analysis was done, factors that still have statistically significant were pre-operative Hb level and surgical technique. We found that patients with pre-operative Hb level <12 g/dl have the risk of blood transfusion more than patients with Hb >12 g/dl for 5.1 times (OR_{adj}= 5.10, 95%CI: 2.26-11.48). Patients undergone CAS technique have risk of transfusion 0.15 times less than who with conventional technique (OR_{adj}= 0.15, 95%CI: 0.06-0.40). (Table 4)

Discussion

This study demonstrates that pre-operative Hb level < 12 g/dl increase risk of the need for blood transfusion after total knee arthroplasty. Similarly, several studies have shown the significant of pre-operative Hb level that influence on the required for blood transfusion in TKA[13,14].

Salido et al. demonstrated patients with preoperative Hb level less than 110 g/L had a 100% transfusion rate[14], and Pierson et al. found an increasing of preoperative Hb level was most effective in reducing transfusion rate[13]. We can strongly conclude that patients with preoperative Hb level < 12 g/dl may need for blood transfusion after TKA.

Table 2:

Factors associated with blood transfusion (n=190)

Factors	Blood transfusion				p-value
	Yes		No		
	n	%	n	%	
Age					
40-49	1	(100.0)	0	(0.0)	0.144*
50-59	6	(17.6)	28	(82.4)	
60-69	18	(23.1)	60	(76.9)	
70-79	21	(30.9)	47	(69.1)	
≥ 80	4	(44.4)	5	(55.6)	
Gender					
Male	6	(20.0)	24	(80.0)	0.392
Female	44	(27.5)	116	(72.5)	
BMI					
Normal/preobesity	41	(28.5)	103	(71.5)	0.232
Class I-II (30-40)	9	(19.6)	37	(80.4)	
Underlying disease					
Hypertension					
No	10	(27.8)	26	(72.2)	0.825
Yes	40	(26.0)	114	(74.0)	
Diabetes mellitus					
No	34	(23.4)	111	(76.6)	0.107
Yes	16	(35.6)	29	(64.4)	
Dyslipidemia					
No	26	(25.2)	77	(74.8)	0.715
Yes	24	(27.6)	63	(72.4)	
Cardiopathy					
No	43	(25.1)	128	(74.9)	0.272
Yes	7	(36.8)	12	(63.2)	
Other Underlying disease					
No	43	(25.0)	129	(75.0)	0.295*
Yes	7	(38.9)	11	(61.1)	
Knee side					
Right	24	(25.8)	69	(74.2)	0.537*
Left	24	(25.8)	69	(74.2)	
Both	2	(50.0)	2	(50.0)	

Table 2:

Factors associated with blood transfusion (n=190) (Continued)

Factors	Blood transfusion				p-value
	Yes		No		
	n	%	n	%	
ASA Classification					
ASA Class I	2	(16.7)	10	(83.3)	0.573
ASA class II	41	(26.1)	116	(73.9)	
ASA class III	7	(33.3)	14	(66.7)	
Pre-operative Hb level (g/dl)					
< 12	31	(53.4)	27	(46.6)	< 0.001
12-13	12	(20.7)	46	(79.3)	
> 13	7	(9.5)	67	(90.5)	
Surgical Technique					
Conventional	29	(37.2)	49	(62.8)	0.002
Computer assist	9	(12.5)	63	(87.5)	
Minimal invasive	12	(30.0)	28	(70.0)	
Arthrotomy approach					
Mid vastus	43	(23.9)	137	(76.1)	0.004*
Medial parapatella	7	(70.0)	3	(30.0)	
Tranexamic acid					
Use	40	(24.5)	123	(75.5)	0.172
nonuse	10	(37.0)	17	(63.0)	
Intra-operative systolic blood pressure (Initial)					
101-120 mmHg	5	(27.8)	13	(72.2)	0.634*
121-140 mmHg	17	(22.7)	58	(77.3)	
141-160 mmHg	25	(30.9)	56	(69.1)	
161-180 mmHg	3	(18.8)	13	(81.3)	
Postoperative DVT prophylaxis					
No use	23	(34.3)	44	(65.7)	0.060
ASA	11	(35.5)	20	(64.5)	
Apixaban	9	(18.4)	40	(81.6)	
Dabigatran	7	(16.3)	36	(83.7)	
Preoperative diagnosis					
Primary OA	48	(26.5)	133	(73.5)	1.000
Inflammatory OA	1	(33.3)	2	(66.7)	
Revision knee	1	(16.7)	5	(83.3)	

Table 2:

Factors associated with blood transfusion (n=190) (Continued)

Factors	Blood transfusion				p-value
	Yes		No		
	n	%	n	%	
Operative time					
< 1 Hour	1	(5.0)	19	(95.0)	0.066
1-2 Hours	47	(29.2)	114	(70.8)	
2-3 Hours	2	(22.2)	7	(77.8)	
Surgeon experience					
Yes	33	(21.9)	118	(78.1)	0.006
No	17	(43.6)	22	(56.4)	
Use of drainage					
Yes	49	(26.3)	137	(73.7)	1.000
No	1	(25.0)	3	(75.0)	

Table 3:

Univariable analysis for factors associated with blood transfusion by logistic regression analysis (n=190) (Continued)

Factors	Blood transfusion				OR	95%CI	p-value
	Yes		No				
	n	%	n	%			
Age							
< 60	7	(20.0)	28	(80.0)	1.00	Reference	
60-69	18	(23.1)	60	(76.9)	1.20	(0.45-3.20)	0.716
≥ 70	25	(32.5)	52	(67.5)	1.92	(0.74-5.00)	0.180
Gender							
Male	6	(20.0)	24	(80.0)	1.00	Reference	
Female	44	(27.5)	116	(72.5)	1.52	(0.58-3.96)	0.394
BMI							
Normal/pre-obesity (18.5-30)	41	(28.5)	103	(71.5)	1.00	Reference	
Class I-II (30-40)	9	(19.6)	37	(80.4)	0.61	(0.27-1.38)	0.235
Hypertension							
No	10	(27.8)	26	(72.2)	1.00	Reference	
Yes	40	(26.0)	114	(74.0)	0.91	(0.40-2.06)	0.825
Diabetes mellitus							
No	34	(23.4)	111	(76.6)	1.00	Reference	
Yes	16	(35.6)	29	(64.4)	1.80	(0.88-3.71)	0.110

Table 3:

Univariable analysis for factors associated with blood transfusion by logistic regression analysis (n=190) (Continued)

Factors	Blood transfusion				OR	95%CI	p-value
	Yes		No				
	n	%	n	%			
Dyslipidemia							
No	26	(25.2)	77	(74.8)	1.00	Reference	
Yes	24	(27.6)	63	(72.4)	1.13	(0.59-2.16)	0.715
Cardiopathy							
No	43	(25.1)	128	(74.9)	1.00	Reference	
Yes	7	(36.8)	12	(63.2)	1.74	(0.64-4.69)	0.277
Other Underlying disease							
No	43	(25.0)	129	(75.0)	1.00	Reference	
Yes	7	(38.9)	11	(61.1)	1.91	(0.70-5.23)	0.209
Knee side							
Right	24	(25.8)	69	(74.2)	1.00	Reference	
Left	24	(25.8)	69	(74.2)	1.00	(0.52-1.93)	1.000
Both	2	(50.0)	2	(50.0)	2.88	(0.38-21.55)	0.304
ASA Classification							
ASA Class I	2	(16.7)	10	(83.3)	1.00	Reference	
ASA class II	41	(26.1)	116	(73.9)	1.77	(0.37-8.41)	0.474
ASA class III	7	(33.3)	14	(66.7)	2.50	(0.43-14.66)	0.310
Pre-operative Hb level (g/dl)							
≥ 12	19	(14.4)	113	(85.6)	1.00	Reference	
< 12	31	(53.4)	27	(46.6)	6.83	(3.36-13.87)	< 0.001
Surgical Technique							
Conventional	29	(37.2)	49	(62.8)	1.00	Reference	
Computer assist surgery	9	(12.5)	63	(87.5)	0.24	(0.11-0.56)	0.001
Minimal invasive surgery	12	(30.0)	28	(70.0)	0.72	(0.32-1.64)	0.439
Arthrotomy approach							
Mid vastus	43	(23.9)	137	(76.1)	1.00	Reference	
Medial parapatella	7	(70.0)	3	(30.0)	7.43	(1.84-30.00)	0.005
Tranexamic acid							
use	40	(24.5)	123	(75.5)	1.00	Reference	
nonuse	10	(37.0)	17	(63.0)	1.81	(0.77-4.27)	0.176
Intraoperative systolic blood pressure (Initial)							
≤ 140 mmHg	22	(23.7)	71	(76.3)	1.00	Reference	
> 140 mmHg	28	(28.9)	69	(71.1)	1.31	(0.68-2.51)	0.416

Table 3:

Univariable analysis for factors associated with blood transfusion by logistic regression analysis (n=190) (Continued)

Factors	Blood transfusion				OR	95%CI	p-value
	Yes		No				
	n	%	n	%			
Postoperative DVT prophylaxis							
No use	23	(34.3)	44	(65.7)	1.00	Reference	
ASA	11	(35.5)	20	(64.5)	1.05	(0.43-2.57)	0.911
Apixaban	9	(18.4)	40	(81.6)	0.43	(0.18-1.04)	0.061
Dabigatran	7	(16.3)	36	(83.7)	0.37	(0.14-0.97)	0.042
Preoperative diagnosis							
Primary osteoarthritis knee	48	(26.5)	133	(73.5)	1.00	Reference	
Inflammatory osteoarthritis knee	1	(33.3)	2	(66.7)	1.39	(0.12-15.63)	0.792
Revision total knee arthroplasty	1	(16.7)	5	(83.3)	0.55	(0.06-4.86)	0.594
Operative time							
< 1 Hour	1	(5.0)	19	(95.0)	1.00	Reference	
≥ 1 Hours	49	(28.8)	121	(71.2)	7.69	(1.00-59.06)	0.050
Surgeon experience							
Yes	33	(21.9)	118	(78.1)	1.00	Reference	
No	17	(43.6)	22	(56.4)	2.76	(1.32-5.8)	0.007
Use of drainage							
Yes	49	(26.3)	137	(73.7)	1.00	Reference	
No	1	(25.0)	3	(75.0)	0.93	(0.10-9.17)	0.952

Table 4:

Multivariable analysis of factors associated with blood transfusion by multiple logistic regression analysis. (n=190)

Factors	Univariable analysis			Multivariable analysis		
	OR[1]	95%CI	p-value	OR_{adj} [2]	95%CI	p-value
Pre-operative Hb level (g/dl)						
≥ 12	1.00	Reference		1.00	Reference	
< 12	6.83	(3.36-13.87)	< 0.001	5.10	(2.26-11.48)	< 0.001
Surgical Technique						
Conventional	1.00	Reference		1.00	Reference	
Computer assist surgery	0.24	(0.11-0.56)	0.001	0.15	(0.06-0.4)	< 0.001
Minimal invasive surgery	0.72	(0.32-1.64)	0.439	0.60	(0.23-1.6)	0.306

Note: OR, Odds Ratio; ORadj, Adjusted Odds Ratio; CI, confident interval.

[1] Crude Odds Ratio estimated by Simple Logistic regression.

[2] Adjusted Odds Ratio estimated by Multiple Logistic regression (backward stepwise likelihood ratio method) adjusted for Pre-operative Hb level, and surgical Technique. Variable was included in multivariable model due to have p-value < 0.050 in univariable analysis.

"Computer-assisted surgery is highly recommended in TKR to save blood", conclusion by Conteduca F. from his prospective randomize control study. They found that calculated total blood loss of conventional TKA group and CAS-TKA group were difference at 297 ml with statistically significant ($p = 0.0283$)[19], but did not shown the result in blood transfusion. In this study, we found that CAS-TKA have risk of blood transfusion 0.15 times less than conventional technique. This result was corresponded to Conteduca F. So, patients who undergoing CAS-TKA may not need for pre-operative crossmatching PRC.

There are previous studies show that other factors associated with an increased need for blood transfusion include age >75 years, male gender, BMI <27 kg/cm2 and hypertension[16], but some study still not show. In this study, age, gender, BMI, ASA classification, hypertension are shown no statistically significant by using both chi-square test and logistic regression analysis. Gender have shown no statistically significant in this study (p-value 3.92) maybe due to low number of male patient and compare with female is 1:5(30/160), but some studies report in the same result, so author think that it may not associated to blood transfusion same as BMI and hypertension.

In present, many hospital, medical center used preoperative blood management program for increasing Hb level before TKA. The systematic review by Donat R. Spahn et al. demonstrated the used of iron- or erythropoietin-based preoperative blood management interventions reduced rate of transfusion from 11-48%[17]. This study found rate of blood transfusion after TKA at Vajira hospital is 26.3% in the time that we do not have official guideline for blood management. We believed rate of transfusion will be reduced if we use it. However, in post-operative period, level of Hb may not be the best criteria for blood transfusion. Tavares Cardozo et al. reported that reduced of Hb more than 20% may create clinical of tissue hypoperfusion in post-op TKA patients[18], but there is no result about functional outcome. So, the next interesting issue will be relation about blood loss, blood transfusion and functional outcomes.

If blood transfusion rate reduced, the need for pre-operative crossmatching for blood component will be reduced too. So, the study about cost, benefits or value of pre-operative crossmatching blood component in patients whom undergoing elective total knee arthroplasty would be done too.

Limitations of this study include retrospective study design, low number of patients and uncontrolled many factors. Low number of patients may did not allow further subgroup analysis and uncontrolled factors may influence the result but it is real clinical situations that clinicians have to encountered. However, one of the strengths of this study is that the investigation was perform in consecutive patients in an everyday clinical setting without selection bias.

Conclusion

The preoperative hemoglobin level < 12 g/dL was shown to increase risk of the need for blood transfusion after knee arthroplasty, while computer assist surgery was shown to decrease risk of blood transfusion. We suggest that patients with preoperative hemoglobin < 12 g/dL need to be crossmatching PRC in pre-operative steps, while patients with preoperative hemoglobin ≥ 12 g/dL and undergoing CAS-TKA were not necessary to crossmatching PRC before surgery.

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Comparison of the Speech Performance of Thai Adults with Apraxia of Speech and Thai Adults with Normal Speech by Using the Apraxia Test for Thai Adults

Pitcharpa Dejket BSc[1]
Jeamjai Jeeraumporn PhD[1*]
Sumalee Dechongkit PhD[1]
Montip Tiensuwan PhD[2]

[1] Department of Communication Sciences and Disorders, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand
[2] Department of Mathematics, Faculty of Science, Mahidol University, Bangkok, Thailand
* Corresponding author, e-mail address: jeamjai.jee@mahidol.ac.th
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Abstract

Objective: To measure and analyze the speech performance score of adults with apraxia of speech (AOS) and adults with normal speech and to compare the speech performance scores of both groups.

Methods: The study was conducted at the Speech Clinic in Ramathibodi Hospital. Participants were divided into two groups. The measurements of speech performance were obtained by using the Apraxia Test for Thai Adults. The test results were analyzed by using descriptive statistics and a Mann-Whitney U test for a comparison of the speech performance scores of both groups.

Results: The results showed that the group of adults with normal speech had higher scores on all subtests than the group of adults with apraxia of speech (AOS). The results also showed that the group of adults with normal speech had statistically significant differences (p-value < .05) on subtests I, II, III, IV, and some tasks in subtests V, VI, and VII. The group of adults with AOS had more difficulties with both speech and nonspeech tasks than the group of adults with normal speech.

Conclusion: Adults with AOS showed the adverse effects of the impairment on their speech performance scores. They had more difficulties in moving their articulators to produce speech sounds while adults with normal speech did not have impaired movements of their articulators or restricted speech production.

Keywords: apraxia of speech, apraxia test, speech performance

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การศึกษาเปรียบเทียบความสามารถทางการพูดของผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดและผู้ใหญ่ที่พูดปกติโดยใช้แบบประเมินภาวะเสียการรู้ปฏิบัติด้านการพูดฉบับภาษาไทย

พิชญ์อาภา เดชเกตุ วท.บ.[1] **เจียมใจ จีระอัมพร ปร.ด.**[1*]
สุมาลี ดีจงกิจ Ph.D.[1] **มนต์ทิพย์ เทียนสุวรรณ Ph.D.**[2]

[1] ภาควิชาวิทยาศาสตร์สื่อความหมายและความผิดปกติของการสื่อความหมาย คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล กรุงเทพมหานคร ประเทศไทย

[2] ภาควิชาคณิตศาสตร์ คณะวิทยาศาสตร์ มหาวิทยาลัยมหิดล กรุงเทพมหานคร ประเทศไทย

* ผู้ติดต่อ, อีเมล: jeamjai.jee@mahidol.ac.th

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาการแสดงออกทางการพูดในกลุ่มผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดและกลุ่มผู้ใหญ่ที่พูดปกติ โดยใช้แบบประเมินภาวะเสียการรู้ปฏิบัติด้านการพูดฉบับภาษาไทย เพื่อเปรียบเทียบความสามารถในการแสดงออกทางการพูดในกลุ่มผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดและกลุ่มผู้ใหญ่ปกติ

วิธีดำเนินการวิจัย: การศึกษานี้ศึกษาในผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดจำนวน 7 คน และในผู้ใหญ่ที่พูดปกติจำนวน 36 คน อายุระหว่าง 25 ถึง 72 ปี นับตั้งแต่วันที่เริ่มทำการศึกษา แบบประเมินภาวะเสียการรู้ปฏิบัติด้านการพูดฉบับภาษาไทยประกอบด้วยแบบทดสอบย่อยจำนวน 7 แบบทดสอบ โดยผู้ประเมินจะพูดบอกให้ผู้เข้าร่วมวิจัยทุกรายปฏิบัติตามข้อคำสั่งในแต่ละข้อเรียงลำดับตามในแต่ละแบบทดสอบย่อย การวิเคราะห์ทางสถิติใช้สถิติเชิงพรรณนา ได้แก่ ค่าเฉลี่ย ส่วนเบี่ยงเบนมาตรฐานและพิสัยในการหาค่าคะแนนการแสดงออกทางการพูดของกลุ่มตัวอย่างทั้งสองกลุ่ม สถิติทดสอบแมน-วิทนีย์ ยู ใช้เพื่อเปรียบเทียบคะแนนการแสดงออกทางการพูดในทั้งสองกลุ่ม

ผลการศึกษา: ค่าคะแนนการแสดงออกทางการพูดในกลุ่มผู้ใหญ่ที่พูดปกติมีค่าสูงกว่ากลุ่มผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดในทุกแบบทดสอบย่อย ผลการศึกษายังแสดงให้เห็นว่า ในกลุ่มผู้ใหญ่ที่พูดปกติมีค่าคะแนนที่สูงกว่าอย่างมีนัยสำคัญทางสถิติในแบบทดสอบย่อยที่ 1 (การควบคุมอวัยวะที่ใช้ในการพูดโดยอัตโนมัติ) แบบทดสอบย่อยที่ 2 (การเคลื่อนไหวอวัยวะที่เกี่ยวข้องกับการพูดอย่างตั้งใจ) แบบทดสอบย่อยที่ 3 (การทดสอบภาวะเสียการรู้ปฏิบัติในการควบคุมอวัยวะในช่องปาก) แบบทดสอบย่อยที่ 4 (การทดสอบภาวะเสียการรู้ปฏิบัติในการควบคุมแขนขา) บางหัวข้อในแบบทดสอบย่อยที่ 5 (การลากเสียงสระและอัตราการเคลื่อนไหวอวัยวะในการออกเสียงอย่างเป็นลำดับ) แบบทดสอบย่อยที่ 6 (การพูดตาม) และแบบทดสอบย่อยที่ 7 (การพูดต่อเนื่องและการพูดอย่างอัตโนมัติ) ที่ระดับความเชื่อมั่น 0.05 ($p < 0.05$)

สรุป: กลุ่มผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดมีความบกพร่องในคะแนนความสามารถทางการพูดโดยมีความลำบากในการเคลื่อนไหวอวัยวะที่ใช้ในการพูดมากกว่ากลุ่มผู้ใหญ่ที่มีการพูดปกติ

คำสำคัญ: การพูดอะแพรกเซีย, แบบทดสอบอะแพรกเซีย, การแสดงออกทางการพูด

วันที่รับบทความ 28 มิถุนายน 2564 **วันแก้ไขบทความ** 29 พฤศจิกายน 2564 **วันตอบรับบทความ** 1 มีนาคม 2565

Introduction

Apraxia of speech (AOS) is an impairment in speech production caused by damage in the neurological systems that control speech. This impairment occurs in both speech programming and speech sequencing of the articulators. Apraxia of speech is not related to weakness, slowness, or coordination of the articulators. This disorder directly affects voluntary speech but does not affect reflex and automatic speech[1-2]. Apraxia of speech is caused by brain injury from a stroke which lesion in the frontal lobe[1,3] or parietal lobe, or a subcortical lesion in the left hemisphere[3].

Duffy reported that AOS was identified in eight percent of 6,101 adults with motor speech disorders at the Mayo Clinic in the United States[4]. In Thailand, the patient statistical data from Information department of Ramathibodi Hospital for 2015 showed that 16.5% of all patients with neurological disorders in Speech Clinic had AOS. Based on the prevalence of AOS, it is not a common disorder when compared to other speech problems caused by motor speech disorders.

Apraxia of speech affects the speech characteristics of people in several aspects: 1) articulation, 2) rate and prosody, 3) fluency, 4) other speech characteristics such as alternating motion rates (AMRs) and sequential motion rates (SMRs).

The AOS test in the Thai language was initially developed in 1988 by Akamanon and, in 2002, Sarankawin studied in Thai normal adults aged 20-65 in order to determine its reliability. The reliability of this test was adequate (0.71-0.97 (p-value<.05))[5]. Although the reliability of the AOS test was adequate for adults with normal speech, the AOS test was not used to evaluate adults with AOS. Accordingly, there were no speech performance scores from these adults with AOS. Therefore, the present research evaluated the speech performance scores of Thai adults with apraxia of speech. Moreover, this AOS test was administered to Thai adults with the normal speech in order to compare the speech performance scores of both groups.

Methods

Study design and participants

The study was conducted at the Speech Clinic in Ramathibodi Hospital from August 2016 to October 2017. The samples sizes calculated using the two independent means. The ratio of normal speech versus AOS groups set at 4:1 (36:9 participants). There were 36 adults with normal speech, but there were only 7 instead of 9 adults with AOS because 2 adults with AOS were excluded from the study. Because they could not reach the inclusion criteria. In addition, participants with AOS could not be found more at that time. All Thai adults with AOS in this study had aphasia with varying degrees of severity. They were diagnosed by speech and language pathologist using WAB test. The duration of illness, it was 2 to 30 months, the mean duration of illness was 15.14 months. Adults with pure AOS were not patients in the Speech Clinic at that time because pure AOS is rare. The eligible adults with AOS were able to produce at least 3 long syllables per sentence and could follow at least 1-step commands. The age range of adults with AOS was from 41 to 69 years, the mean age was 55.55 years. For the group of adults with normal speech, the participants did not have any prior speech problems such as stuttering, cluttering or other voice disorders and did not have a history of neurological problems. The group of adults with normal speech were matched for age as closely as possible with the adults who had apraxia of speech. The age range of adults with normal speech was from 25 to 72 years, the mean age was 53.74 years. All of the participants in this study were Central Thai Native speakers and they demonstrated normal hearing ability during a conversation with the researcher. These participants did not have a history of psychiatric problems, a history of delayed speech and

language development, or articulation disorders. The demographic data of participants are shown in Table 1.

Instruments

The instruments used in this study consisted of the Apraxia Test for Thai Adults and its record form[5], a video recorder was used for, and video clips were investigated when there was any suspicious output in the recorded data, and a stopwatch was used for measuring time durations. The Apraxia Test for Thai Adults consisted of seven subtests as follow:

Subtest I: Automatic control of articulators such as coughing, sneezing, and chewing. This subtest included 10 items.

Subtest II: Voluntary movement such as protruding the tongue, showing teeth, and puffing the cheeks. This subtest included 9 items.

Subtest III: Oral apraxia is an impairment of nonspeech volitional movements of the lips, tongue, jaw, and other articulators[4]. Rounding the lips, smiling, and clicking the tongue are examples of the evaluation tasks. This subtest included 30 items.

Subtest IV: Limb apraxia is an impairment of the purposive motions of the upper and/or lower limbs that are related to left frontal hemisphere damage without association with weakness, sensory impairment, loss of coordination of movements, or lack of comprehension of commands[6-8]. Clapping hands, waving a hand, and standing on one leg are examples of the evaluation tasks for limb apraxia. This subtest included 15 items.

Subtest V: Vowel prolongation and diadochokinetic rate. This subtest included 7 items and was divided into 2 parts. The diadochokinetic rate is a speech task that is concerned with the repetition of syllables consisting of consonants and vowels[9]. The diadochokinetic rate consists of 2 tasks: 1) for alternating motion rate (AMR), participants were asked to produce sounds such as /p^hɤ-p^hɤ-p^hɤ/, /t^hɤ-t^hɤ-t^hɤ/, /k^hɤ-k^hɤ-k^hɤ/ in 5 seconds for each sound, 2) for sequential motion rate (SMR), participants were asked to produce sounds /p^hɤ-t^hɤ-k^hɤ/ in 5 seconds[9-14].

Subtest VI: Repetition. This subtest included 34 items and was divided into 4 tasks. The tasks in this subtest are repetitions of monosyllabic words, multisyllabic words, words with increasing lengths, and sentences.

Table 1:
Details of demographic data of adults with AOS (n=7)

No.	Gender	Age (years-months)	Type of aphasia	Duration of illness (months)
1	Male	57-0	Anomic	30
2	Male	50-2	Anomic	2
3	Male	59-6	Global	17
4	Male	67-0	Wernicke's	20
5	Male	69-9	Global	25
6	Male	41-1	Anomic	3
7	Male	44-1	Global	9

Subtest VII: Spontaneous speech and automatic speech. This subtest included 6 items and was divided into 2 parts. For spontaneous speech, the participant produced contextual speech by describing a picture. For automatic speech, the participant was asked to count from 1 to 20 and tell the days of the week forwards and backwards, forwards and backwards.

Procedure

The test session began with subtest I and continued through subtest VII. For subtests I, III, and IV, each participant was asked to follow commands. The participant's responses were scored. If the participant did not understand or did not respond, the command was repeated only once. If the participant did not respond again, the item was omitted. For subtest II, the participant was asked to move their articulators following the presentation of the target by the researcher and to respond. If the participant did not respond, the articulator movement was demonstrated only once. If the participant did not respond again, the item was omitted. For subtest V: Vowel prolongation, the participant was asked to take a deep breath and then prolong vowel sounds as long as he/she could. The times of vowel prolongations were recorded. For diadochokinetic rate, the participant was asked to produce /p^hɤ/, /t^hɤ/, /k^hɤ/ and /p^hɤ-t^hɤ-k^hɤ/ sounds in 5 seconds. The rate of repetition responses was recorded. For subtest VI, the participant was asked to repeat certain words one time. If the participant did not understand or did not respond, the researcher repeated words only once. If the participant did not respond or respond incorrectly, the item was omitted. For the first part of subtest VII: Spontaneous speech and automatic speech, the participant was asked to describe a picture. For the second part, the participant was asked to count from 1 to 20 forwards and backwards. After that, the participant was told to name the days of the week forwards and backwards and their responses were recorded.

The scoring system of each subtest was shown in Table 2-5.

Ethical consideration

This study was approved by the Ethical Clearance Committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University (ID 08-59-16). The participants, or close relatives of participants who were willing to participate in this study, were informed about the purposes of this study and the procedure for administering the Apraxia Test for Thai Adults. They were required to sign the informed consent form.

Table 2:
The scoring system of the Apraxia Test for Thai Adults for Subtest I and subtest II.

Score	Response
2	Immediately correct response or correct response after incorrect response.
1	Partially correct response.
0	Incorrect response or no response.

Table 3:

The scoring system of the Apraxia Test for Thai Adults for Subtest III and subtest IV.

Score	Response
11	Immediately correct response.
10	Accurate response but delayed not to exceed 5 seconds.
9	Correct response after incorrect response.
8	Partially correct response.
7	Multiple responses to a command.
6	Articulatory groping, trial and error before a correct response.
5	Incorrect response.
4	Articulatory groping, trial and error but an incorrect response.
3	Repeat the preceding command.
2	Irrelevant responses and less attention.
1	No response.
0	No awareness.

Table 4:

The scoring system of the Apraxia Test for Thai Adults for Subtest VI.

Score	Response
2	The immediately correct response, effortlessly produced sounds.
1	Self-correction, delayed, trying to produce sounds, one or more articulatory errors.
0	No response or failed to attempt to produce the word but no sound or incorrect response without awareness of sounds.

Table 5:

The scoring system of the Apraxia Test for Thai Adults for Subtest VII.

Score	Response
3	Produce two-word phrases or four-word sentences, using appropriate grammar.
2	Partially correct response.
1	Articulatory errors, trial-and-error response.
0	No response.

Statistical analysis

The data were categorized and analyzed by using SPSS for Windows, version 24.0. Descriptive statistics, including means and standard deviations, were used to describe the speech performance scores of both groups. The Mann-Whitney U test was used to compare the differences in means relative to the speech performance scores of adults with apraxia of speech and adults with normal speech. The level of significance was set at .05.

Results

The speech performance scores of adults with apraxia of speech and adults with normal speech and the differences in the speech performance scores of both groups are shown in Table 6.

Table 6:

Means, standard deviations, and the comparison of speech performance scores between adults with apraxia of speech and adults with normal speech and by using the Mann-Whitney U test.

No. of subtest	Subtests	Total score	Normal (n = 36)		AOS (n = 7)		Z	p-value
			Mean	S.D.	Mean	S.D.		
I	Automatic control of articulators	20.00	19.97	0.17	14.86	3.63	-6.11*	.00
II	Voluntary movement	54.00	54.00	0.00	48.43	4.32	-5.90*	.00
III	Oral apraxia	330.00	326.42	3.99	258.71	41.34	-4.31*	.00
IV	Limb apraxia	165.00	165.00	0.00	140.86	26.61	-5.32*	.00
V	Vowel prolongation (seconds)							
	/a:/		13.58	2.14	11.71	3.55	-1.23	.22
	/u:/		13.33	2.72	12.86	4.74	-.66	.51
	/i:/		13.36	2.43	12.00	5.10	-1.39	.16
	Diadochokinetic rate (times/5 secs)							
	/p^hɤ/		19.11	1.97	17.43	4.20	-1.56	.12
	/t^hɤ/		18.69	2.51	15.43	3.16	-2.39*	.02
	/k^hɤ/		17.61	2.51	15.86	4.22	-1.16	.25
	/p^hɤ-t^hɤ-k^hɤ/		11.78	2.17	6.43	2.82	-3.70*	.00
VI	Repetition	108.00	107.56	0.91	72.14	23.97	-4.87*	.00
VII	Spontaneous speech and automatic speech	14.00	14.00	0.00	8.43	2.70	-6.45*	.00

* Significant at p-value < 0.05, AOS = apraxia of speech, Z = Z-test

The mean speech performance scores of adults with AOS for subtest I was 14.86 points out of 20.00 points, for subtest II was 48.43 points out of 54.00 points, for subtest III was 258.71 points out of 330.00 points, for subtest IV was 140.86 points out of 165.00 points. For subtest V, the mean prolongation time for /a:/ was 11.71 seconds, for /u:/ 12.86 seconds, and for /i:/ 12.00 seconds, and the mean times per 5 seconds for /p^hɤ/ was 17.43 times, for /t^hɤ/ 15.43 times, for /k^hɤ/ 15.86 times, and for /p^hɤ-t^hɤ-k^hɤ/ 6.43 times. For subtest VI, 72.14 points out of 108.00 points, and for subtest VII 8.43 points out of 14.00 points.

The mean speech performance scores of adults with normal speech for subtest I was 19.97 points out of 20.00 points, for subtest II was 54.00 points out of 54.00 points, for subtest III was 326.42 points out of 330.00 points, for subtest IV was 165.00 points (full score), for subtest V, mean prolongation time for /a:/ was 13.58 seconds, for /u:/ 13.33 seconds, and for /i:/ 13.36 seconds, and the mean times per 5 seconds for /p^hɤ/ was 19.11 times, for /t^hɤ/ 18.69 times, for /k^hɤ/ 17.61 times, and for /p^hɤ-t^hɤ-k^hɤ/ 11.78 times. For subtest VI, 107.56 points out of 108.00 points, for subtests VII, 14.00 points out of 14.00 points. For subtests II, IV, and VII, the mean speech performance scores of adults with normal speech were full.

The mean speech performance scores of adults with AOS and adults with normal speech were analyzed by using the Mann-Whitney U test to compare the differences. This comparison showed that differences in speech performance scores of both groups were statistically significant for subtests I, II, III, and IV (p-value = 0.00 for each subtest), subtest V: Diadochokinetic rates for /t^hɤ/ and /p^hɤ-t^hɤ-k^hɤ/ (p-value = 0.02, p-value = 0.00), subtest VI (p-value = 0.00), and subtest VII (p-value = 0.00). There were statistically nonsignificant differences between the scores of the adults in the AOS group and the adults in the normal speech group for subtest V: Vowel prolongation /a:/, /u:/, /i:/, and diadochokinetic rates of /p^hɤ/ and /k^hɤ/.

Discussion

For subtest I: Automatic control of articulators, the mean speech performance score of adults with AOS was less than the mean score of adults with normal speech. The difference in mean scores between the two participant groups was statistically significant. The results of this subtest disagreed with the results of Duffy[4] and McNeil et al.[15] who reported that adults with AOS produced normal automatic movements[4, 15]. However, the adults with AOS in the present study had aphasia. In the study of Square-Storer et al., adults with AOS plus aphasia had impairments in movements of articulators and had difficulty in carrying out the required automatic control movements while the adults with pure AOS were normal regarding those processes[16].

For subtest II: Voluntary movement, the mean speech performance score of adults with AOS was less than the mean score of adults with normal speech. The difference in mean scores between the two groups was statistically significant. The adults with AOS in the present study had problems with voluntary movements in terms of accuracy, speed, and strength of movement. The results of this subtest agreed with the results of Code[17], McNeil et al.[18]. They reported that the voluntary movements of adults with AOS were impaired[17-18]. The results of adults with normal speech agreed with those of Sarankawin[5] and McNeil et al.[15]. They reported that adults with normal speech could move their articulators correctly[5,15]. Adults with normal speech did not have an impairment restricting voluntary movements[5], while adults with AOS had problems with the intended movements[15,19] although they had normal neuromuscular control[17].

For subtest III: Oral apraxia, the mean speech performance score of adults with AOS was less than the mean score of adults with normal speech. The

difference in mean scores between the two groups was statistically significant. The adults with AOS in the present study had problems with this subtest in different degrees. The results of this subtest agreed with the results of Duffy[4], Ziegler[20], McCaffrey[21], DeRenzi et al.[22], and LaPointe and Wertz[23]. They reported that oral apraxia was common among adults with AOS[4, 20-23]. The results of adults with normal speech who did not receive a full score agreed with those of Sarankawin[5]. She reported that most tasks in this subtest were used in daily life and were easy to do but some tasks were not used in daily life so they were difficult to do properly[5]. The task 'furling the sides of the tongue' is an inherited genetic ability so some participants in her study could not do this. Sturtevant reported results which showed that seventy percent of adults could furl the sides of their tongue[24].

For subtest IV: Limb apraxia, the mean speech performance score of adults with AOS was 140.86 points. The adults with normal speech received the full score. The difference in mean scores between the two groups was statistically significant. The results of the present study agreed with the results of Roy et al.[6] who reported that adults with normal speech received higher scores than adults with AOS[6], and adults with AOS also had limb apraxia[4]. Although adults with AOS may have limb apraxia, two adults with AOS in the present study received a full score. The results of some adults with AOS in the present study possibly occurred from aphasia which affected language comprehension and body movement[25]. Because of stroke, adults with aphasia in the present study also had unilateral weakness. Accordingly, they had problems with coordination and balance, and with speech abnormality. However, the most common symptoms of adults with AOS were not related to weakness, slowness, and coordination of movements[1,2, 26].

For subtest V: Vowel prolongation and diadochokinetic rate. The mean vowel prolongation time for /a:/, /u:/, /i:/ of adults with AOS was less than the mean time of adults with normal speech, but the difference in mean times between the two groups was statistically nonsignificant. Vowel prolongation of adults with AOS was normal or near normal because these adults had impairments of movements and coordination of their articulators but not relative to weakness, slowness, or incoordination of the speech mechanism[1,4]. The results of vowel prolongation tasks agreed with those in the study of Ogar et al. They reported that adults with AOS had less difficulty in vowel prolongation because it was a simple task for adults with AOS[27]. Regarding diadochokinetic rate, which consisted of measuring the alternating motion rates (AMRs) and the sequential motion rates (SMRs), the mean number of times per 5 seconds for /p^hɤ/, /t^hɤ/, /k^hɤ/, and /p^hɤ-t^hɤ-k^hɤ/ of adults with AOS were 17.43, 15.43, 15.86 and 6.43 times respectively, and of adults with normal speech were 19.11, 18.69, 17.61, and 11.78 times respectively. The differences in the mean number of times per 5 seconds of both groups for /t^hɤ/ and /p^hɤ-t^hɤ-k^hɤ/ were statistically significant, while the differences in the mean number of times per 5 seconds of both groups for /p^hɤ/ and /k^hɤ/ were statistically nonsignificant. These results agreed with those of Mlcoch and Square[28]. They reported that adults with AOS had more difficulty in articulating a lingua-dental sound (/t^hɤ/) than other types of articulation. Accordingly, the adults with AOS in their study could not articulate properly[28]. Adults with AOS in the present study had more difficulty with SMRs than AMRs. These results agreed with the results of Darley et al. and Duffy. They reported that adults with AOS had more impairments in sequential movements (SMRs) than in repeating the same movements (AMRs.)[1, 4]. Josephs et al. reported that the speech rates of adults with AOS were slow and also had distortions in their SMRs when compared to their AMRs[2].

For subtest VI: Repetition, the mean speech performance score of adults with AOS was 72.14 points and was 107.56 points for adults with normal speech. The difference in mean scores between the two groups was statistically significant. Adults with AOS in the present study had problems in repeating words and sentences and made more errors in repeating multisyllabic words than single words. These results agreed with the results of McNeil et al., Ogar et al., and Ziegler. They reported that adults with AOS made errors when they repeated words or sentences[18, 27, 29]. The results of this subtest also agreed with the results of Darley et al., Duffy, Ogar et al., and Mlcoch et al. They reported that adults with AOS made more errors in producing complex words and sentences[1, 4, 27, 28].

For subtest VII: Spontaneous speech and automatic speech, the mean speech performance score of adults with AOS was less than the mean score of adults with normal speech. The difference in mean scores between the two groups was statistically significant. For the spontaneous speech task, the results showed that all adults with AOS had problems with telling a story from a picture. In general, severe AOS restricted the completion of spontaneous speech tasks[4]. Moreover, all AOS participants in the present study had aphasia. Adults with aphasia had reduced or limited spontaneous speech[30]. Thus, the adults with AOS in the present study had an apparent narrative impairment. On the second task, automatic speech, only one adult with AOS received a full score. Other adults with AOS did not have a problem in counting forward from 1 to 20 and telling the days in a week consecutively but they had problems counting from 1 to 20 backwards and telling the days in a week backwards. Counting from 1 to 20 backwards and telling the days in a week backwards were regarded as intentional speech. This meant that these adults with AOS had difficulty with their automatic speech, backward counting, and telling the days in a week than simply counting forward from 1 to 20 and telling the days in a week. The results on the second task, automatic speech, agreed with the explanations of Darley et al., Darley and Spriestersbach, and Duffy. They reported that automatic speech (counting forwards and telling the day forwards) of adults with AOS was easier to articulate than intentional speech (counting backwards and telling the day backwards)[1, 4].

Conclusion

A comparison of the speech performances of adults with normal speech and adults with apraxia of speech showed statistically significant differences on subtests I, II, III, IV, and on some tasks of subtests V, VI, and VII. The results of this study might be used as a guideline for screening and preparing of treatment plans. However, the numbers of adults with AOS in this study were small and there was no participant of pure AOS. Therefore, a future study should have more adults with AOS in order to collect enough data to better evaluate their speech performance test scores, and participants with pure AOS should be included in order to study the characteristics of pure AOS.

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Conflict of interest

No likely conflict of interest relevant to this article was reported.

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Outcome of Self-Efficacy Enhancement Program on Knowledge and Confidence of Foot Ulcers Prevention Behavior in the Diabetic Elderly of the Puranawat Temple Elderly Club, Bangkok

Kunnika Jermtienchai PhD[1*]
Prapaiwan Danpradit MEd[1]

[1] College of Nursing and Health, Suan Sunandha Rajabhat University, Bangkok, Thailand
* Corresponding author, e-mail address: kunnika.je@ssru.ac.th
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Abstract

Objectives: To study and compare knowledge of foot ulcer prevention before and after program implementation and to compare foot ulcers prevention behavior before program implementation and confidence of foot ulcers prevention behavior after program implementation in the diabetic elderly of the Puranawat Temple Elderly Club, Bangkok.

Method: The research was quasi experimental research with one group pre-post-test design. The purposively selected samples were thirty Diabetic elderly of the Puranawat Temple Elderly Club, Bangkok. The research tool was the modified program of the Self-Efficacy Theory of Bandura. Data were collected from questionnaire for the period of 3 days. Data were analyzed by percentage, mean, standard deviation and paired t-test.

Results: Before and after program implementation, the diabetic elderly had good and very good level of knowledge about foot ulcers prevention respectively. After program implementation, the knowledge about foot ulcer prevention of the samples were statistical significantly higher than before the program ($p < 0.01$).

Results of the compare the foot ulcers prevention behavior before program implementation. The samples had average level of behavior before program implementation. After program implementation, they had high level of confidence which was higher than the level of behavior before program implementation with statistical significance ($p \leq 0.01$) in overall and in each aspect. The aspect with the highest confidence was foot examination and the aspect with the least confidence was foot cleaning.

Conclusion: The Self-Efficacy Enhancement Program on knowledge and confidence of foot ulcers prevention behavior in the diabetic elderly of the Puranawat Temple Elderly Club showed significant improvement of knowledge and confidence in the diabetic elderly. The program was designed for health teams, village health volunteers and other interested groups to enhance foot care self-efficacy and help the diabetic elderly in communities to prevent foot ulcers and leg amputation.

Keywords: Foot ulcers prevention, Diabetic elderly, Self-Efficacy Enhancement Program

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ผลของโปรแกรมการส่งเสริมสมรรถนะตนเองต่อความรู้และความมั่นใจในพฤติกรรมการป้องกันการเกิดแผลที่เท้า ผู้สูงอายุเบาหวานในชมรมผู้สูงอายุวัดปุรณาวาส กรุงเทพมหานคร

กรรณิกา เจิมเทียนชัย ค.ด.[1*]

ประไพวรรณ ด่านประดิษฐ์ ค.ม.[1]

[1] วิทยาลัยพยาบาลและสุขภาพ มหาวิทยาลัยราชภัฏสวนสุนันทา กรุงเทพมหานคร ประเทศไทย

* ผู้ติดต่อ, อีเมล: kunnika.je@ssru.ac.th

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาและเปรียบเทียบความรู้เกี่ยวกับการป้องกันการเกิดแผลที่เท้า ก่อนและหลังเข้าร่วมโปรแกรม ฯ และเปรียบเทียบพฤติกรรมการป้องกันการเกิดแผลที่เท้า ก่อนเข้าร่วมโปรแกรม ฯ กับความมั่นใจในพฤติกรรมการป้องกันการเกิดแผลที่เท้าหลังเข้าร่วมโปรแกรม ฯ ผู้สูงอายุเบาหวานในชมรมผู้สูงอายุวัดปุรณาวาส กรุงเทพมหานคร

วิธีการศึกษา: รูปแบบวิจัย: กึ่งทดลอง กลุ่มเดียว วัดผลก่อนและหลังการทดลอง กลุ่มตัวอย่าง คือ ผู้สูงอายุเบาหวานในชมรมผู้สูงอายุวัดปุรณาวาส กรุงเทพมหานคร ซึ่งสุ่มเลือกแบบเจาะจง จำนวน 30 คน เครื่องมือวิจัยคือโปรแกรมการประยุกต์ใช้ทฤษฎีการรับรู้สมรรถนะตนเองของแบนดูรา เก็บรวบรวมข้อมูลด้วยแบบสอบถาม ดำเนินการวิจัยจำนวน 3 วัน วิเคราะห์ข้อมูลด้วยค่าร้อยละ ค่าเฉลี่ย ค่าเบี่ยงเบนมาตรฐาน และ paired t-test

ผลการวิจัย: ผู้สูงอายุเบาหวาน มีความรู้เกี่ยวกับการป้องกันการเกิดแผลที่เท้าในระดับดี หลังเข้าร่วมโปรแกรม มีความรู้การป้องกันการเกิดแผลที่เท้าในระดับดีมาก และดีกว่าก่อนเข้าร่วมโปรแกรมอย่างมีนัยสำคัญทางสถิติ ($p \leq 0.01$)

ผลการเปรียบเทียบพฤติกรรมการป้องกันการเกิดแผลที่เท้าก่อนเข้าร่วมโปรแกรมกับความมั่นใจในพฤติกรรมการป้องกันการเกิดแผลที่เท้าหลังเข้าร่วมโปรแกรม ผลการวิจัยพบว่ากลุ่มตัวอย่างก่อนเข้าร่วม โปรแกรมมีพฤติกรรมการป้องกันการเกิดแผลที่เท้าในระดับปานกลาง หลังเข้าร่วมโปรแกรมมีความมั่นใจในพฤติกรรมการป้องกันการเกิดแผลที่เท้าในระดับมากและมากกว่าก่อนเข้าร่วมโปรแกรมอย่างมีนัยสำคัญทางสถิติ ($p < 0.01$) ทั้งในภาพรวมและรายด้าน และด้านที่มีความมั่นใจสูงสุด คือ ด้านการสำรวจเท้า ด้านที่มีความมั่นใจต่ำสุด คือ ด้านการดูแลรักษาความสะอาดเท้า

สรุป: โปรแกรมการส่งเสริมสมรรถนะตนเองต่อความรู้และความมั่นใจในการป้องกันการเกิดแผลที่เท้า ผู้สูงอายุเบาหวานในชมรมผู้สูงอายุวัดปุรณาวาส พบว่าผู้สูงอายุเบาหวานมีความรู้และความมั่นใจมากขึ้น และโปรแกรมฯ ออกแบบสำหรับทีมสุขภาพ อาสาสมัครสาธารณสุขประจำหมู่บ้าน และผู้สนใจอื่นๆ ที่จะนำไปใช้แนะนำผู้สูงอายุเบาหวานแหล่งอื่นๆ ในการส่งเสริมสมรรถนะตนเองในการดูแลเท้าและป้องกันการเกิดแผลที่เท้าและการถูกตัดขา

คำสำคัญ: การป้องกันการเกิดแผลที่เท้า, ผู้สูงอายุเบาหวาน, โปรแกรมการส่งเสริมสมรรถนะตนเอง

วันที่รับบทความ 16 กรกฎาคม 2564 **วันแก้ไขบทความ** 21 มีนาคม 2565 **วันตอบรับบทความ** 7 เมษายน 2565

Introduction

At present, the non-communicable diseases (NCDs) among Thai people are increasing with continuous upward trend. The four common NCDs are diabetes mellitus, coronary heart disease, cerebrovascular disease and chronic obstructive pulmonary disease[1]. Diabetes, one of the most common NCDs, has complications which decrease patients' quality of life. The complications include several organs such as peripheral neuropathy, diabetic retinopathy, cardiovascular disease, chronic kidney disease, diabetic foot, etc.[2] Data from International Diabetes Federation (IDF) in 2017 showed that there were 425 million people globally who had diabetes. There were 98 million diabetic people in the 65 years and over group and 327 million diabetic people in the 20-64 years group. It is estimated that by 2045 there will be 629 million people with diabetes worldwide with the majority of them are the elderly aged 65 and over. The continuous upward trend in Thailand during 2016 to 2018 showed that there were 840,489, 876,970 and 941,226 diabetic patients respectively[3]. It was also found that only 30 % of the diabetic elderly were able to control their blood sugar to an appropriate level. This caused a huge loss in the cost of healthcare in Thailand on which the country had to spend; for example, 47,596 million baht was spent annually for diabetes alone[1].

Poor blood sugar control in the diabetic elderly could result in complications, especially diabetic foot. This consequently leads to loss of limbs since prolonged hyperglycemia affects large and small arteries. There are damages of peripheral nervous system and peripheral arteries of legs and feet which cause abnormal sensation of extremities. Wound healing is delayed due to decreased blood supply. And if the wound is severely infected, the patient may need to have a foot or leg amputated. The data from IDF revealed that the diabetic elderly had 25 times risk of limb amputation and 70 % of the amputation was caused by diabetes[4]. Therefore, diabetic foot complication is a serious health condition and the health teams should work together to help the elderly with diabetes to be able to take proper care of their feet. There was evidence that 85 % of leg loss from diabetes could be preventable if the patients' feet were examined and properly taken care of at the initial stage. Therefore, proper foot care behavior could reduce and delay complications and risks of leg and foot amputations[4-5], particularly in the disadvantaged elderly group. In Bangkok, there were many elderly who live near the temples. The elderly in the Puranawat Temple Elderly Club live near the Puranawat Temple which is the undeveloped area in the north perimeter of Bangkok. They have less opportunity[6-9] for income[7-8], education[6-7], and health service accessibility[7-9]. The health care teams could help promote foot care behavior to prevent complication of amputation. At present, there are 150 elderly in the Puranawat Temple Elderly Club which 51 of them have diabetes. Most of them have mild symptoms but are vulnerable to have diabetic foot. Proper foot care should be enhanced early because if diabetes lasts for more than 5 years without proper treatment and foot care, it can lead to diabetic foot and serious complications. A 5-year retrospective review of literatures related to the prevention of foot ulcers in the diabetic elderly (2013-2017) found that the Self-Efficacy Theory of Bandura[10] was applied to the diabetic elderly to enhance self-efficacy in foot care and resulted in better foot care behavior of foot ulcer prevention after program implementation. The examples included the research of Janpech P, Puncha-Glingasorn P, Srinoi W[11], Iamsomboon T, Kengganpanich T, Kengganpanich K, Benjakul S[12] and Phanphuech P[13]. This indicated that the application of the Self-Efficacy Theory of Bandura[10] was effective for use in experiments. The researchers are interested in the outcome of Self-Efficacy Enhancement program on knowledge and confidence of foot ulcers prevention behavior in the diabetic elderly of the Puranawat Temple Elderly Club, Bangkok.

Objectives

1. To study and compare knowledge of foot ulcer prevention before and after program implementation in the diabetic elderly.

2. To compare foot ulcers prevention behavior before program implementation with the confidence of foot ulcers prevention behavior after program implementation in the diabetic elderly.

Methods

Research design: quasi-experimental, one-group, pre- and post-test.

Study population: 51 from 150 elderly of the Puranawat Temple Elderly Club, Bangkok who had history of diabetes mellitus in 2020.

Study samples: The selection criteria were the followings: age 60 years and older, regardless of gender, diagnosed by a doctor as having type 1 and/or type 2 diabetes, good consciousness, not dependent, could provide information on their own, voluntarily and willing to participate in research project. The sample size was calculated by G* power 3.01 Program, the level of statistic power of test = .80, effect size = 0.5 and significant confidence =< 0.5. The calculated samples of 27 were added with 10% of the samples to compensate for sample loss to be 30 total samples[14]. The sampling method was purposive sampling.

Research tools:

1. Experiment tool: The Self-Efficacy Enhancement Program on knowledge and confidence of foot ulcers prevention behavior in the diabetic elderly of the Puranawat Temple Elderly Club, Bangkok was modified by the researchers from the Self-Efficacy Theory[10] and from literature review of related research. It consisted of 4 aspects: 1) Creating successful experiences through lecture of knowledge on prevention of foot ulcers in diabetes 2) Presentation of model with the Diabetes Guide and Foot Care Guide to prevent foot ulcers constructed by the researchers, 3 sets of video media and group demonstration with return-demonstration 3) motivational talk and 4) emotional stimulation.

2. Monitoring tools consisted of:

2.1 Experiment time plan was set for 3 days with 3 hours per day. The experiment site was the Puranawat Temple Elderly Club, Bangkok.

2.2 The models used to create experiences to enhance self-efficacy in knowledge and confidence of foot ulcers prevention behavior after program implementation included media guides and 3 sets of Video.

- The media guides were the Diabetes Guide[15] and Foot Care Guide which were developed by the researchers from review of related research. They were the teaching materials which contained knowledge, picture and details for home study after program implementation.

- The 3 sets of Video consisted of Video media set 1 (Diabetes)[16], Video media set 2 (Caring for the foot of the elderly with diabetes)[17] and Video media set 3 (Caring for the foot of the elderly with diabetes)[18]. The video media demonstrated real pictures of diabetic elderly who had foot problems and might need amputation. The foot care and treatment were the visual from hospital setting.

3. Data collection tool was the questionnaire constructed by the researchers and consisted of 4 parts. Part 1 was general data of the samples with multiple choice answers and filling in the blanks. Part 2 contained questions of knowledge related to causes, signs and risks of foot ulcers and limb amputation from diabetes. There were 16 questions which each question had answer choices to choose from, right (1 point) or wrong (0 point). Part 3 was the questionnaire for foot ulcers prevention behavior constructed by the researchers. It consisted of 3 rating scales as: 3 for routine practice, 2 for some practice and 1 for least practice. There were 24 questions of 4 aspects. 1) 6 questions for foot cleaning, 2) 5 questions for foot examination, 3) 8 questions for foot care to prevent foot ulcers and 4) 5 questions for blood circulation stimulation of foot. Part 4 was the questionnaire for confidence

of foot ulcers prevention behavior. It consisted of 3 rating scales as: 3 for routine practice, 2 for some practice and 1 for least practice. There were 24 questions of 4 aspects. 1) 6 questions for foot cleaning, 2) 5 questions for foot examination, 3) 8 questions for foot care to prevent foot ulcers and 4) 5 questions for blood circulation stimulation of foot.

Quality of research tools

1. Content validity. The questionnaires for knowledge of foot ulcers prevention, foot ulcers prevention behavior and confidence of foot ulcers prevention behavior were assessed for content validity by an expert in Adult Nursing and two nurse practitioners who worked for diabetic foot care. The researchers corrected the questionnaires as the experts' suggestion and determined the Content Validity Index (CVI) from the questions with Indicators of Compromise (IOC) >= 0.66.

2. Reliability The researchers conducted the tryout of the corrected questionnaires in 20 Diabetic elderly in the community of Wat Thaiyawas, Nakornchaisri District, Nakornprathom which was adjacent to Wat Puranawat. The questionnaire for knowledge of foot ulcers prevention was tested by Kuder-Richardson Formula 20 (KR-20) and showed reliability of 0.92. The questionnaire for foot ulcers prevention behavior and the confidence to prevent foot ulcers behavior were tested with Cronbach's alpha coefficient and showed reliability of 0.89 and 0.90 respectively.

Interpretation of the scores

1. Score levels of knowledge on foot ulcers prevention were determined for 3 levels as: very good was a score of 14.00-16.00 (80-100 %), good was a score of 12.00-13.99 (70.00-79.99%), average was a score of 10.00-11.99 (60.00-69.99%), low was a score of 8.00-9.99 (50.00-59.99%) and very low was a score lower than 8.00 (50% and below).

2. Score levels of foot ulcers prevention behavior and confidence of foot ulcers prevention behavior were determined for 3 levels as: Good was a score of 2.51-3.00, average was a score of 1.51-2.50 and low was a score of 1.00-1.50.

Program implementation and data collection

There were 3 activities, taking a total time of 9 hours, with details as the followings:

Activity 1 Day 1 (3 hours): Creating successful experiences by lecture of knowledge of foot ulcer prevention in diabetes with the media of the Diabetes Guide and Foot Care Guide to prevent foot ulcers.

Activity 2 Day 2 (3 hours): 1. Presentation of models from the videos of foot care in diabetes. The samples watched 3 sets of video presentation: Video media set 1 (Diabetes)[16], Video media set 2 (Caring for the foot of the elderly with diabetes)[17] and Video media set 3 (Caring for the foot of the elderly with diabetes)[18]. 2. After each video presentation, the researchers repeatedly described and highlighted the causes of foot ulcers and amputation.

Activity 3 Day 3 (3 hours): 1. Presentation of models in groups of 10 samples through demonstration and return-demonstration regarding foot cleaning, foot examination, foot care to prevent foot ulcer and blood circulation stimulation of foot.

2. Reviewing knowledge of diabetes and foot care to prevent diabetic foot ulcers by randomly asking each sample the questions that most of them answered incorrectly and repeating explanations.

3. Reflection by having the samples share their opinions from the questions that they answered incorrectly. The researchers explained answers and reviewed the topics again. During the process, the emotional support was used to increase confidence in foot care practice.

4. Lecture and reviewing knowledge of diabetes and foot care practice skills with summary of important points. The Diabetes Guide and Foot Care Guide to prevent foot ulcers were used as reference materials with focus on topics that the samples answered the questions incorrectly.

5. During the lecture, the researchers used motivational talk words and emotional stimulation

to raise the samples' awareness of the importance and necessity of diabetes knowledge and confidence that they could change their behavior in taking care of their feet when they had diabetes.

Statistics for data analysis

1. General information was analyzed by percentage.

2. Data and comparison of knowledge of the samples regarding foot ulcer prevention, before and after program intervention, were analyzed by mean, standard deviation (SD) and paired t-test.

3. Compare of foot ulcers prevention behavior before program implementation with the confidence of foot ulcers prevention behavior after program implementation were analyzed by mean, standard deviation (SD) and paired t-test.

Protecting the samples' rights

This research was approved with a certificate of ethics, code COA.1-051/2021 by Suan Sunandha Rajabhat University and the researchers conducted the research with protection of confidentiality and impact of the participants throughout the research process.

Results

General information of the 30 diabetic elderly showed that there were 14 samples (46.62%) who were 66-70 years old. There were 23 female samples (76.59%), 16 samples (53.30%) were married/ living with spouse, 18 samples (60.00%) finished primary school education, 11 samples (36.63%) had income of 1,000-3,000 Baht/month and 20 samples (66.70%) had 5-9 years duration of diabetes. During the past 2 years, there were 27 samples (89.90%) who never had foot ulcers and 19 samples (63.27%) who never received diabetes knowledge from the health teams before.

Before and after program implementation, the diabetic elderly had good and very good level of knowledge about foot ulcers prevention respectively. After program implementation, the knowledge about foot ulcer prevention of the samples were statistical significantly higher than before the program ($p < 0.01$) as Table 1.

Results of behavior and confidence: The samples had average level of foot ulcers prevention behavior before program implementation. After program implementation, they had high level of confidence of foot ulcers prevention behavior which was higher than the behavior before program implementation with statistical significance ($p \leq 0.01$) as Table 2.

After program implementation, the samples had higher level of confidence of foot ulcers prevention behavior before program implementation with statistical significance ($p \leq 0.01$) in all items of foot ulcer prevention behavior. The highest level of confidence was found in foot examination. The lowest level of confidence was found in foot cleaning as Table 3.

Table 1:

Levels of knowledge and comparison of knowledge in foot ulcer prevention of the diabetic elderly before and after program implementation (n=30)

Items	Total score	$\bar{X}$	SD	Level	paired t-test
Knowledge in foot ulcer prevention					
After program implementation	16	13.66	1.66	Very good	5.01**
Before program implementation	16	11.20	2.34	Good	

**Difference with statistical significance ($p \leq 0.01$)

Table 2:

Comparison of foot ulcers prevention behavior before program implementation and the confidence after program implementation of the diabetic elderly (n=30)

Items	Total score	$\bar{X}$	SD	Level	paired t-test
Confidence after program implementation	3	2.69	0.27	High	6.70**
Behavior before program implementation	3	2.04	0.41	Average	

**Difference with statistical significance ($p \leq 0.01$)

Table 3:

Comparison of foot ulcers prevention behavior before program implementation and the confidence after program implementation, classified by aspects of foot ulcers prevention behavior (n=30)

Aspects	Total Score	$\bar{X}$	SD	Level	Paired t-test
1. Foot cleaning					
- Confidence after program implementation	3	2.59	0.45	High	3.64**
- Behavior before program implementation	3	2.18	0.49	Average	
2. Foot examination					
- Confidence after program implementation	3	2.77	0.31	High	4.48**
- Behavior before program implementation	3	2.17	0.56	Average	
3. Foot care to prevent foot ulcers					
- Confidence after program implementation	3	2.69	0.31	High	6.38**
- Behavior before program implementation	3	1.96	0.49	Average	
4. Stimulation of blood circulation of foot					
- Confidence after program implementation	3	2.73	0.33	High	6.83**
- Behavior before program implementation	3	1.89	0.57	Average	

**Difference with statistical significance ($p \leq 0.01$)

Discussion

In general, the research results showed that the diabetic elderly had good level of knowledge in foot ulcer prevention behavior before program implementation. After program implementation, the knowledge was very good and was higher than the knowledge before program implementation with statistical significance ($p \leq 0.01$). This was consistent with the research of Janpech P, Puncha-Glingasorn P, Srinoi W[11] which found that people with diabetes had good level of knowledge in foot care before participating in the experimental program. After the experiment, the mean knowledge was very good and significantly higher than the knowledge before the experiment ($p \leq 0.01$). However, it was not consistent with the research of Chusak T, Sasang N, Chaleoykitti S[19], Sasee T, Benja Muktabhant B, Uttamavatin P[20], Prachanno W, Ratree Aramsin R, Gadudom P[21] and Srimaksook K[22] which found that the diabetic patients had average knowledge of foot care. It could be implied that

most diabetic elderly had average knowledge in foot ulcer prevention. According to the statistics from the International Diabetes Federation, elderly people with diabetes were 25 times more at risk of amputation than those without diabetes. Foot ulcers were associated with people with uncontrolled diabetes or improper self-care behaviors[4-5].

The comparison of foot ulcers prevention behavior and confidence of foot ulcers prevention behavior showed that after program implementation, the diabetic elderly had more confident to prevent foot ulcers than the behavior before program implementation with statistical significance ($p \leq 0.01$). It was consistent with our hypothesis and with the modified program of the Self-Efficacy Theory of Bandura[10] to promote behavior of foot care for foot ulcer prevention in the diabetic elderly. The Self Efficacy Theory of Bandura explained that the people who were in needs and had high self-confidence to perform with expected results would tend to practice or were confident to practice. The theory suggested that a successful experience had to be built through lecture and model presentation from the real patients or from the media in order to build practice confidence. This research program included lecture on the knowledge of foot ulcer prevention, 2 media guides, the Diabetes Guide and Foot Care Guide, and 3 sets of video media. The video media were the models of real pictures of the diabetic elderly, who had foot problems with risk of amputation, and the management of diabetes in the hospital. The samples also participated in demonstration and return demonstration to enhance their practical skills. The skills of foot ulcer prevention included foot cleaning, foot examination, foot care to prevent foot ulcers and stimulation of blood circulation of foot. The Diabetes Guide and Foot Care Guide were handed out to the samples to review their knowledge at home. The program resulted in increase of confidence of the diabetic elderly in foot ulcer prevention. The research results were consistent with the research of many people who applied the concept of applying Bandura's self-efficacy theory to prevent foot ulcers among diabetic elderly and diabetic patients in different area. After the experiment had knowledge and behavior to prevent foot ulcers higher than before[11-13]. It shows that the application of Bandura's self-efficacy theory can be applied to prevent foot ulcers in other groups of diabetic elderly.

Conclusion

The Self-Efficacy Enhancement Program on knowledge and confidence of foot ulcers prevention behavior in the diabetic elderly of the Puranawat Temple Elderly Club showed significant improvement of knowledge and confidence in the diabetic elderly. The program was designed for health teams, village health volunteers and other interested groups to enhance foot care self-efficacy and help the diabetic elderly in communities to prevent foot ulcers and leg amputation.

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- ลักษณะทางคลินิกและผลการรักษาของโรคมะเร็งเม็ดเลือดขาวเฉียบพลันชนิดมัยอีลอยด์ การศึกษาแบบย้อนหลัง 9 ปี ในโรงพยาบาลวชิรพยาบาล
  (Clinical Characteristics and Outcomes of Acute Myeloid Leukemia in Vajira Hospital-a 9-year Single Center Retrospective Study)
- ผลการรักษาของผู้ป่วยมะเร็งเต้านมที่ได้รับการรักษาแบบสงวนเต้านมในคณะแพทยศาสตร์วชิรพยาบาล: การศึกษาย้อนหลัง 10 ปี
  (Treatment Outcomes after Breast Conserving Therapy in Breast Cancer Patients in Faculty of Medicine, Vajira Hospital: a 10-Year Retrospective Study)
- ความถูกต้องในการใช้ liver imaging reporting and data system ฉบับ 2018 (LI-RADS version 2018) ในการวินิจฉัยมะเร็งตับในผู้ป่วยที่มีภาวะตับแข็ง, ผู้ป่วยที่มีภาวะพาหะตับอักเสบบี เรื้อรัง, ผู้ป่วยที่เคยเป็นมะเร็งตับมาก่อนและรักษาแล้ว จากภาพเอกซเรย์สนามแม่เหล็กไฟฟ้า เปรียบเทียบกับผลชิ้นเนื้อ
  (Diagnostic Accuracy of the Liver Imaging Reporting and Data System (LI-RADS 2018) in Diagnostic of Hepatocellular Carcinoma in Cirrhosis Patients, Chronic Hepatitis B Carrier Patient, Prior Hepatocellular Carcinoma Patient and Treated Hepatocellular Carcinoma Patient Compared with Histopathological Report)
- ความสะอาดของลำไส้และผลข้างเคียงของการใช้ Sodium Phosphate และ Polyethylene Glycol สำหรับเตรียมลำไส้ในผู้ป่วยที่ได้รับการเตรียมลำไส้ใหญ่แบบนอนในวชิรพยาบาล
  (Efficacy and Adverse Effects of Sodium Phosphate and Polyethylene Glycol When Used in Bowel Preparation prior to Colonoscopy among Patients Admitted at Vajira Hospital)
- ความสัมพันธ์ระหว่างการทำนายความเสี่ยงต่อการเกิดโรคหลอดเลือดหัวใจโดยใช้คะแนนความเสี่ยงการเป็นโรคหลอดเลือดหัวใจของประชากรไทยและคะแนนความเสี่ยงของการเป็นโรคหลอดเลือดหัวใจ จากการศึกษา MESA ในผู้ป่วยไทย
  (The Correlation between Thai Cardiovascular Risk Score and the Multi-Ethnic Study of Atherosclerosis (MESA) Risk Score in Thai Populations)
- ปัจจัยเสี่ยงต่อการให้เลือดทดแทนในผู้ป่วยที่ได้รับการผ่าตัดเปลี่ยนข้อเข่าเทียม
  (Risk Factors of Blood Transfusion in Knee Arthroplasty)
- การศึกษาเปรียบเทียบความสามารถทางการพูดของผู้ใหญ่ที่มีภาวะเสียการรู้ปฏิบัติด้านการพูดและผู้ใหญ่ที่พูดปกติ โดยใช้แบบประเมินภาวะเสียการรู้ปฏิบัติด้านการพูดฉบับภาษาไทย
  (Comparison of the Speech Performance of Thai Adults with Apraxia of Speech and Thai Adults with Normal Speech by Using the Apraxia Test for Thai Adults)
- ผลของโปรแกรมการส่งเสริมสมรรถนะตนเองต่อความรู้และความมั่นใจในพฤติกรรมการป้องกันการเกิดแผลที่เท้าผู้สูงอายุเบาหวานในชมรมผู้สูงอายุวัดปุรณาวาส กรุงเทพมหานคร
  (Outcome of Self-Efficacy Enhancement Program on Knowledge and Confidence of Foot Ulcers Prevention Behavior in the Diabetic Elderly of the Puranawat Temple Elderly Club, Bangkok)

คณะแพทยศาสตร์วชิรพยาบาล มหาวิทยาลัยนวมินทราธิราช

ฝ่ายวิชาการ คณะแพทยศาสตร์วชิรพยาบาล
681 ถนนสามเสน เขตดุสิต กรุงเทพมหานคร 10300
โทร. 0-2244-3522, 0-2668-7088 แฟกซ์ 0-2668-7088