Bias towards dementia: Are hip fracture trials excluding too many patients? A systematic review

Jonah Hebert-Davies a,*, G-Yves Laflamme b,1, Dominique Rouleau b,1, HEALTH and FAITH investigators d

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A B S T R A C T
Patients with hip fractures are older and often present many co-morbidities, including dementia. These patients cannot answer quality of life questionnaires and are generally excluded from trials. We hypothesized that a significant number of patients are being excluded from these studies and this may impact outcomes. This was a two part study; the first analyzing databases of two ongoing large-scale multi-centred hip fracture trials and the second a systematic review. The FAITH and HEALTH studies were analyzed for exclusion incidence directly related to dementia. The second part consisted of a systematic search of all relevant studies within the last 20 years. In the FAITH study, a total of 1690 subjects were excluded, 375 (22.2%) of which were due to dementia or cognitive impairment. In the HEALTH study, 575 were excluded with dementia/cognitive impairment representing 207 patients (36%). Following the systematic review, 251 articles were identified 17 of which were retained. The overall prevalence of dementia was 27.9% (range 2–51%). Only two studies compared demented and non-demented groups. In these studies significant increases in both mortality and complications were found. In summary, when investigating hip fractures, choosing appropriate objective endpoints is essential to ensure results are also applicable to patients with dementia.

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Introduction
Hip fractures in the elderly are frequent, occurring approximately 250,000 times a year in the United States and about 30,000 times a year in Canada.1 Over the past 20 years, numerous randomized controlled surgical studies have tried

to answer various questions about these fractures. During this time, evidence-based orthopaedics using functional outcome scores has become a mainstay of research. Very large, multi-centred studies have become necessary to demonstrate statistically significant differences in treatment options. Consequently, the associated cost of such trials has skyrocketed. Patients afflicted with these fractures are older and often present many co-morbidities, including dementia. These patients cannot answer quality of life questionnaires and are generally excluded from trials.

We hypothesized that on this basis, a significant number of subjects were excluded from hip fracture studies. We also believed
that if primary outcomes for such trials were objective (such as reoperations, the “Timed up and go”[2] or similar tests) rather than subjective and that dementia exclusion criteria were eliminated, the number of patients excluded at screening would drop. The primary objective of this study was to evaluate the number of patients with dementia excluded from large hip fracture trials. The secondary objective was to determine what, if any, impact excluding these patients may have on results in these trials.

Methods

This was a two part study with the first part aimed out evaluating the incidence of dementia in hip fracture patients and the second a systematic review of the literature. We used the databases of two ongoing large-scale multi-centred hip fracture trials conducted with the support of the International Hip Fracture Research Collaborative (IHFRC). We chose these specific studies because the participation of our group in these trials made the information readily available. However, because the studies were ongoing, they were not included in the systematic review. The FAITH (Fixation Using Alternative Implants for the Treatment of Hip Fractures) study compares sliding hip screw and multiple cancellous screws for femoral neck fractures. This large multi-centred trial is recruiting patients in Canada, the United States, the Netherlands, Norway, India and Australia. Patients receive either treatment based on central randomization. Primary outcome is reoperation rate, but both function and quality of life are secondary outcomes. Among the exclusion criteria are: “Moderate or severe cognitive impairment” and “history of frank dementia.” We chose to look at patients with dementia or cognitive impairment because in many studies the two are used interchangeably. Also there are many similarities between the two on a functional basis. This however, does not include patients developing delirium before or after surgery.

The HEALTH study compares total hip arthroplasty (THR) and hemi-arthroplasty for displaced femoral neck fractures. It is currently in an active recruitment phase in Canada, the United States and the Netherlands. The primary outcome for this trial is the revision surgery rate, but again, the secondary outcome is function and quality of life. Patients are assigned to receive either total hip arthroplasty or hemi-arthroplasty by a central randomization centre. Among the exclusion criteria are “Moderate or severe cognitive impairment (Six Item Screener with 3 or more errors)” and “Parkinsons disease (or dementia) severe enough to increase the likelihood of falling”.

All exclusions were tallied for both studies and compared with total enrolment. Enrolment data from all centres were analyzed and compared, to evaluate for possible pre-exclusion.

Following this, we chose to systematically review the hip fracture literature to see if a similar exclusion pattern could be found. We performed a search of the Pubmed and EMBASE databases with the terms “Hip Fracture” “surgery” and “randomized controlled trial” to identify all relevant studies. As previously mentioned, no ongoing trials were included. Only articles with abstracts in either English or French and published between January 1st 1990 and January 1st 2011 were retained. The remaining abstracts were evaluated for inclusion. All trials not comparing surgical treatment or not involving randomized trials were excluded. Then, all included articles were obtained and evaluated by two different authors. Studies containing no specific information on dementia (incidence or exclusion and inclusion criteria), or including only patients with dementia were not retained. A standardized data extraction form was developed to obtain the following information: fracture type, age inclusion criteria, mean age, gender, dementia incidence, dementia definition, test, mortality at 1, 3, 12 and 24 months, length of study, QOL questionnaires used.

All data were then analyzed using SPSS 18.0 (IBM, Somers, NY). Descriptive statistics were used for the incidence of dementia in included studies. Patient data was extracted using weighted means.

Results

Exclusion rates

As of December 2010, the FAITH study had enrolled a total of 475 patients over a 2-year period. A total of 1690 subjects were excluded for all reasons, 375 of which were due to dementia or cognitive impairment according to criteria mentioned earlier. All patients were screened for cognitive impairment. The patients with dementia represented 22.2% of all exclusions (17.3% of all screened patients). In the HEALTH study, as of September 2010, 210 patients were enrolled and 575 were excluded. In this trial, patients with dementia represented 36% (207 patients) of exclusions (26.3% of all screened patients). When averaged over both studies, these subjects accounted for 25.6% of all exclusions or 19.7% of all patients.

Variability was found among the inclusion practices in the different participating centres. In the FAITH study, Canadian centres enrolled 69 patients and excluded 889, for a 7.2% inclusion rate. In American hospitals, 162 patients were randomized with 847 patients excluded, representing a 16% inclusion rate. Similar variations are seen in the HEALTH trial. In the United States, 37 patients were enrolled out of 129 screened (28.7% inclusion). In the Netherlands, there is a similar, 28% inclusion rate. In Canadian centres, 35 patients were randomized and 249 excluded, for a total of 12.3% enrolment.

Systematic reviews

Following the search of Pubmed and EMBASE databases, 251 articles were identified. After evaluation for inclusion and exclusion criteria, a total of 17 articles were retained.3–18 A flow chart with article selection is seen in Fig. 1. In 13 studies, patients with dementia were included in primary outcomes. The total number of patients in these studies was 3272, with 2424 women. Mean weighted age was 82 (range 75–84). The overall prevalence of dementia was 27.9% (range 2–51%) with the individual exclusion

Fig. 1. Flow chart of the systematic review process for the database search results.
rates for each study seen in Table 1. In only seven trials was a specific test used to identify dementia.

Two of the studies analyzed patients with and without dementia. Johansson et al. compared THR and open reduction and internal fixation (ORIF) for intertrochanteric fractures in 146 patients, of which 56 had dementia. In the THR group, cognitively impaired patients had a higher dislocation rate (29% vs. 8%). In the ORIF group, patients with dementia had a 55% reoperation rate, compared to 20% in those without cognitive impairment. Overall mortality was doubled (46% vs. 23%) in the dementia group. The same research team also published a similar study comparing the treatment of femoral neck fractures.11 In this article, 45 patients with dementia were included. Overall mortality in both groups was quadrupled (44% vs. 11%) in the cognitively impaired. Also, in the THR group, dislocations occurred in 32% of patients with dementia, compared to 12% in other patients.

Discussion

Studying a problem where the target patient population includes a large amount of subjects generally excluded from studies poses a real problem. Patients with hip fractures typically present with several co-morbidities, including dementia. In certain trials, reoperation rate can be used as an objective outcome to measure treatment impact. A perfect example of this is that both the FAITH and HEALTH studies use reoperation rate as their primary outcome. However, patients with dementia are nevertheless excluded because of their inability to provide secondary outcomes, even though data is still collected for patients who develop dementia after initial surgery. Comparing two forms of fixation using reoperation rate as a demonstration of failure is objective. It does not, however, give a sense of functional outcome for these patients. Other trials are less amenable to this type of endpoint.

One major disadvantage of excluding large numbers of subjects from trials is the introduction of bias. Using dementia as an exclusion criterion negatively impacts recruitment for hip fracture clinical trials. This was seen in both HEALTH and FAITH where it was the second most common specific reason for exclusion. Also, there can be a phenomenon of pre-exclusion, where patients are not even considered for randomization because of dementia. This phenomenon might explain the variable rates of inclusion among various centres, as well as differences between countries. The lack of objective criteria used to define dementia in one of the two studies is the likely explanation for these differences and may introduce selection bias.

All the included studies in the systematic review demonstrate the importance of the issue concerning patients with dementia. Keating in 2006 published results on 298 patients, comparing ORIF hemiarthroplasty and total arthroplasty for displaced intracapsular femur neck fractures. Only 13% of eligible patients were randomized, and 30% of those excluded were due to failure of a mini-mental test. Macaulay et al. reported results on hemiarthroplasty and total hip replacement for displaced femoral neck fractures. In this series, 118 patients were screened and 77 excluded, of which 23% due to cognitive impairment. These numbers are not insignificant. As seen in the studies by Johansson et al., patients with dementia tend to have worse outcomes and increased complication rates. Conclusions are drawn from studies where these cases are excluded and then used to guide treatment in other patients afflicted with dementia. The applicability of such conclusions can be questioned.

As evidence-based orthopaedics with multi-centred randomized control trials become the norm, finding the right methods for evaluation becomes key. While functional outcome scores such as the Short-Form 36 (SF-36), Lower Extremity Measure (LEM) and others have proven to be very useful in evaluating quality of life, they all have limitations. Specifically, they cannot be accurately used to evaluate patients with dementia or cognitive impairment. While some questionnaires have been modified for patients with these conditions, none to our knowledge has been validated in fracture or arthroplasty patients with cognitive impairment.

Several studies20,21 have shown that third-person evaluation of quality of life using questionnaires was not representative and therefore proxies should not be used to complete them for research purposes. Physical function tests or validated tools like the “time up and go (TUG)” the 2-min walk test and others all allow third-person evaluation of functionality in hip fracture patients. The TUG test consists of measuring the time it takes for an individual to get up from a chair, walk to a 3-m mark, turn around, come back, and sit down. This has been shown to be both reproducible and valid.22-24 An advantage of these tests is that even those with cognitive impairment can perform them. In summary, when investigating patients with hip fractures, choosing appropriate objective endpoints is essential to avoid over-exclusion. When dealing with patients suffering from these fractures, there is a predictable incidence of cognitive
impairment. Eliminating these common subjects (representing as many as 1 out of 5 elderly patients) from trials can create an unrepresentative population and could be viewed as unintentional discrimination against patients with dementia. Furthermore, our review shows that current literature results may not necessarily be applicable to patients with dementia. Most studies have excluded these patients with fewer than 5% having analyzed this particular sub-group and all of them showing significant impact in outcomes. While validated quality of life scores are useful in assessing results, in this situation they should perhaps be kept for subgroup analysis. Evaluating function with validated tools applicable to patients with dementia would also allow avoid this exclusion. Also, we believe that choosing objective primary outcomes and not excluding patients with dementia could speed up the recruitment process and eventually lower costs.

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Conflict of interest statement

All authors have no relevant disclosures to this study.

Ethical approval

Ethics committee approval was obtained for this study.

Appendix A

A.1. FAITH Investigators

Steering Committee: Mohit Bhandari (chair), Philip J Devereaux, Gordon Guyatt, Martin J Heetveld, Kyle Jeray, Susan Liew, Martin J Richardson, Emil H Schemitsch, Marc Swiontkowski, Paul Tornetta III, Stephen Walter.

Methods Centre and Coordination of Canadian/International Sites Supported under the PSI and CHIR Grants: McMaster University, Hamilton, ON: Mohit, Bhandari, Sheila Sprague, Helena Viveiros, Nicole Simunovic, Marilyn Swinton, Diane Heels- Ancell, Lisa Buckingham, Aravin Durai Kanan.

Country Coordination of US Sites Supported under the NIH Grant: University of Minnesota, Minneapolis, MN: Marc F Swiontkowski, Julie Agel.

Country Coordination of Dutch Sites Supported under the SNO Grant: Erasmus Medical Center, Rotterdam: Esther MM van Lieshout, Stephanie M Zielinski.

Investigators - The Netherlands:

Academic Medical Center, Amsterdam: J Carel Goslings, Robert Haverlag, M J Ponsen.


Erasmus Medical Center, Rotterdam: Peter Patka, Martin Everdijk, Rolf Peters, Oscar van Waes, Dennis den Hartog, O van Waes, P Oprel.


Medisch Centrum Rijnmond Zuid (Renamed as Maastad Ziekenhuis), Rotterdam: Gert R Roukema, H Josaputra, Paul Keller, PP de Rooij, H Kuiken, H Boxma, BJ Cleefkens, Ronald Liem.


Reinder de Graaf Gasthuis, Delft: Maarten van der Elst, Carmen C van der Pol, Martyn van’t Reit, Maarten van der Elst, TM Karsten, MR de Vries, Laurens PS Stassen, N Schep, Ben Schmidt, WH Hoffman.


St Elisabeth Ziekenhuis, Tilburg: Michiel HJ Verhofstad, Joost MR Meijer, Teun van Egmond, FHWM van den Heijden, Jorg van den Brand.

Tergooiziekenhuize, Hilversum: Harm M van der Vis, Martin Campo, Ronald Verhagen, GHR Albers, A Zurcher.

University Medical Center St Radboud, St Radboud: A van Kampen, J Bier, Arie B van Vught, Michael Edwards, Taco Blokhuis, Jan Paul M Frolke, J Geeraidts, JWM Gardeniers, ETCH Tan, LMSJ Poekhette, MC de Waal Malefyt, B Schreurs.

University Medical Center, Utrecht: Roger KJ Simmermacher, Jeroen van Mulken, Karlijn van Wessem, T Blokhuis, Steven M van Gaalen, LPH Leerem.

Ziekenhuis Bronovo, Den Haag: Maarten WGA Bronkhorst, OR Guichierit.

Investigators – Norway:

Ullevaal University Hospital, Oslo: Frede Frithagen, Lars Nordsletten, Thomas Kibsgaard, Knut Jorgen Haug, Tariei Lona, Stein Ugeland, Kenneth Nilsen, Anne Christin Brekke, Elise Berg Vesterhus.

Investigators – Australia:

Royal Brisbane and Women’s Hospital, Herston, QLD: Kevin Tetzworth, Patrick Weinrauch, Paul Pincus, Geoff Donald, Steven yang, Brett Halliday, Trevor Gervais, Michael Holt, Annette Flynn.

Royal Melbourne Hospital, Parkville, VIC: Marinis Pirpiris, David Love, Andrew Bucknill, Richard J Farrugia.

The Alfred, Melbourne, VIC: Susan Liew, Adam Dowrick, Craig Donohue, Harvinder Bedi, Doug Li, Elton Edwards, Steven Csonguray, Russell Miller, Otis Wang, Andrew Chia, Russell Miller, Arvind Jain, Mathan Mammen, Ash Moaveni, Zoe Murdock, Claire Sage.

Investigators – India:

University College of Medical Sciences – Guru Tegh Bahadur Hospital, Delhi: Anil Kumar Jain, Amite Pankaj, Ajay Pal Singh.

Investigators – Colombia:

Fundación Sana Fe, Bogotá: Rodrigo Pesantes, Adriana Martinez, Catherine Novoa.

Investigators – Canada:

Foothills Medical Center, Calgary, AB: Richard E Buckley, Paul Duffy, Robert Korley, Kelly Johnston, Shannon Puloski, Kimberly Carcy.

Henderson Hospital, Hamilton, ON: Victoria Avram.

Kingston General Hospital, Kingston, ON: Ryan Bicknell, Jeff Yach, Davide Bardana, Gavin Wood, Sue Lambert.
London Health Sciences Centre, London, ON: David W Sanders, Jamie Howard, Mark MacLeod, Abdel Lawandy, Debra Bartley, Tim Laney, Christina Tieszer.

McMaster University Medical Centre, Hamilton, ON: Devin Peterson.

Oakville Trafalgar Memorial Hospital, Oakville, ON: Paul Zalzal, Victor Naumentz, Heather Brien, Brad Weening.

Ottawa Hospital – Civic Campus, Ottawa, ON: Eugene K Wai, Steven Papp, Darren Roefy.

Royal Columbian Hospital, New Westminster, BC: Robert McCormack, Trevor Stone, Bertrand Perey, Darius Viskontas, Dory Boyer, Bertrand Perey, Farhad Moola, Mauri Zomar, Karyn Moon, Amber Oatt.

St Michael's Hospital, Toronto, ON: Emil H Schemitsch, Michael McKee, Jeremy Hall, Henry Ahn, Milena R Vicente, Lisa M Wild.

Sunnybrook Health Sciences Centre, Toronto, ON: Hans J Kreder, David JG Stephen, Markku Nousianinen, Ria Cagaanan, Monica Kunz.

Toronto Western Hospital, Toronto, ON: Khalid Syed, Tania Azad.

Queen Elizabeth II Health Sciences Centre, Halifax, NS: Chad Coles, Ross Leighton, David Johnstone, Mark Glazebrook, David Alexander, Cathy Coady, Kelly Trask, Gwendolyn Dobbin.

**Investigators – The USA:**

Boone Hospital Center – Columbia Orthopaedic Group, Columbia, MO: Todd M Oliver, Vicky Jones, James Ronan.

Boston University Medical Center, Boston, MA: Paul Tornetta III, Desmond T Brown, Hope Carlisle, Lisa Shaughnessy.


Duke University Medical Center, Durham, NC: Robert Zura, Maria J Manson.

Greenville Hospital System, Greenville, SC: Kyle Jeray, David Goetz, Scott J Broderick, Scott Porter, Thomas Pace, Stephanie L Tanner, Becky Snider.

Hennepin County Medical Center, Plymouth, MN: Andrew H Schmidt, Jonathan Haas, David Templeman, Jerald R Westberg.

Indiana University - Wishard Health Services, Indianapolis, IN: Brian Mullah, JP Ertl, Karl Shively, Valda Frizel, Molly M Moore.

Lahey Clinic, Burlington, MA: Andrew J Marcantonio, Richard Iorio, Margaret Lobo, Michael Kain, Lawrence Specht, John Tilzey, John Garfi.


MetroHealth Medical Center, Cleveland, OH: Heather A Vallier, John Wilber, Roger G Wilber, John H Sontich, Brendan Patterson, Andrea Dolenc, Chalitha Robinson.

Mission Hospital Research Institute, Asheville, NC: Charles J DePaolo, Rachel Alosky, Leslie E Shell.


OrthoIndy, Indianapolis, IN: Joseph Baele, Tim Weber, Matt Edison, Dana Musapatika.

Orthopaedic Associates of Michigan, Grand Rapids, MI: Clifford Jones, James Ringler, Terrance Endres, Martin Gelbke, Michael Jabara, Debra L Sietsema, Susan M Engerman.

Regions Hospital, St Paul, MN: Julie A Switzer, Mangnai Li, Scott Marston, Peter Cole, Sandy X Vang, Thuan Ly, Sarah Anderson, Amy Foley.

Santa Clara Valley Medical Center, San Jose, CA: Jessica McBeth, Curt Comstock, Navid Ziran.

St Elizabeth Health Center, Youngstown, OH: James Shaer, Barbara Hileman.

St Louis University Hospital, St Louis, MO: David Karges, Lisa Cannada, Djoldas Kuldjanov, John Tracy Watson, James Jackman, Emily Mills, Leslie Hill, Tiffany Simon.

Texas Tech University Health Sciences Center – El Paso, El Paso, TX: Aamr Abdelgawad, Juan Shumia.

Texas Tech University Health Sciences Center – Lubbock, Lubbock, TX: Mark Jenkins, Mimi Zumwalt, Amanda West Romero.

University of Alabama, Birmingham, AL: Jason Lowe, Jessica Goldstein.

University of California Irvine Medical Center, Orange, CA: David P Zamorano, Deanna Lawson.

University of Cincinnati Medical Center, Cincinnati, OH: Michael Archdeacon, John Wyrick, Shelley Hampton.

University of Connecticut, Hartford, CT: Courtland G Lewis, Arben Ademi, Raymond Sullivan, Stephanie Caminiti.

University of Mississippi Medical Center Jackson, MS: Matthew Graves, Lori Smith.


University Orthopaedic Associates, New Brunswick, NJ: Carlos Sagebiel, Patricia Seuffer.


University of Pittsburgh, Pittsburgh, PA: Ivan Tarkin, Peter Siska, Arlene Luther, James Irgang, Dana J Farrell.


University of Texas Health Sciences Center, San Antonio, TX: Animesh Agarwal, Rebecca Wright.

US Army Institute of Surgical Research, Fort Sam Houston, TX: Joseph R Hsu, Gayle M Randall, James R Ficke, Michael Charlton, Mary Fan, Socorro H Garcia.

Vanderbilt University Medical Center, Nashville, TN: William T Ombreskney, Justin Edward Richards, Kenya Robinson.

Wake Forest Medical Center, Winston-Salem, NC: Eben Carroll, Brenda Kulp.

A.2. HEALTH Investigators

**Steering Committee:** Mohit Bhandari, Gordon H Guyatt, Philip James Devereaux, Stephen Walter, Emil H Schemitsch, Thomas A Einhorn, Ken J Koval, Rudolf W Poolman, Martin J Heetveit, Kevin D Tetsworth.

**Methods Centre and Coordination of Canadian/International Sites Supported under the CIHR Grant:** McMaster University, Hamilton, ON: Mohit Bhandari, Sheila Sprague, Nicole Simonovic, Helena Viveiros, Sarah Culgin, Marilyn Swinton, Diane Heels-Ansdell, Lisa Buckingham, Aravind Duraikanan.

**Country Coordination of US Sites Supported under the NIH Grant:** Boston University, Boston, MA: Thomas A Einhorn, Heather Desjardin.
Country Coordination of Dutch Sites Supported under the ZonMw Grant: Erasmus Medical Center, Rotterdam, Esther MM van Lieshout, Paul TPW Burgers.

The Netherlands:
Tergooiziekenhuizen, Hilversum: Harm M van der Vis*, Lijkele Beimers, Jasper de Vries, Arthur W Zurcher, GH Rob Albers, Maarten Rademakers, Stefan Breugem, Ibo van der Haven, Peter Jan Damen, Gythe H Bulstra, Marta C Manto, Mathijs P Somford, Daniel Havercamp.
Flevoziekenhuis, Almere: Mark LM Falke*, Frans J Kurek, Adrianus CH Slingerland.
Gelderse Vallei, Ede: Jan P van Dijk*, Wouter H van Helden.
Norway:
Ullevaal University Hospital, Oslo: Frede Frihagen*, Lars Nordslett, Espen Mauer-Hansen, Berte Boee, Jon Clarke-Jensen, Knut Jorgen Haug, Kenneth Nilsen, Anne Christine Brekke, Elise Bengtsoegaard.
Australia:
Canada:
Foothills Medical Center, Calgary, AB: Richard E Buckley*, Paul Duffy, Robert Korley, Kimberly Carcary.
Hôpital du Sacré-Coeur de Montréal: Yves Laflamme*, Julio C. Fernandes, Marie-France Poirier.
St Michael’s Hospital, Toronto, ON: Emil H Schemitsch*, Earl Bogoch, Jeremy Hall, Henry Ahn, Milena R Vicente.
Queen Elizabeth II Health Sciences Centre: Chad Coles*, Ross Leighton, Glen C Richardson, Michael Biddulph, Michael Gross, Michael Dunbar, Kelly Trask, Gwen Dobbin.
The USA:
Boston University Medical Center, Boston, MA: Thomas A Einhorn*, Jeffrey Zarin, Hari Parvataneni, Heather Desjardin.
Emory University, Atlanta, GA: James R Roberson*, Greg Erens, Antoni Montielonne, Shawndra Woodard
Indiana University - Wishard Health Services, Indianapolis, IN: Brian Mullis*, Janos Ertl, Judd Cummings, Ripley Worman, Mark Webster, Karl Shively, Andrew Parr, Valda Frizzell, Molly Moore.
Mission Hospital Research Institute, Asheville, NC: Charles DePaolo*, Rachel Alosky.
Orthopaedic Associates of Hartford, Rocky Hill, CT: Coudrain Lewis*, Stephanie Caminiti.
Park Nicollet Institute, Minneapolis, MN: Gregg Strathy*, Paul Johnson, Kathleen Peter, Maeghan E. Morton.
Rothman Institute, Philadelphia, PA: Javad Parvizi*, Matthew Austin, Tiffany Morrison.
Rubin Institute, Sinai Hospital, Baltimore, MD: Michael Mont*, Carol Copeland, Ronald Delanos, Harpal Khauna, Shuqaeda Wittington, Madeleine Bacon, Marylou Mullin.

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