GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of October 25 - 29, 2021

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Procalcitonin-Guided Antibiotic Timelines Can Help Decrease Sepsis Sequelae

GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Procalcitonin to Reduce Long-Term Infection-Associated Adverse Events in Sepsis

Kyriazopoulou E, Liaskou-Antoniou L, Adamis G, et al. Procalcitonin to Reduce Long-Term Infection-associated Adverse Events in Sepsis. A Randomized Trial. *Am J Respir Crit Care Med*. 2021; 203(2):202–210. doi:10.1164/rccm.202004-1201OC

KEY TAKEAWAY: Using procalcitonin (PCT) to guide the discontinuation of antibiotics can decrease sepsis-associated adverse events, 28-day mortality, and the cost of hospitalization.

STUDY DESIGN: Multicenter real-world pragmatic randomized control trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: PCT-guided antibiotic discontinuation is a method that has been evaluated only in the setting of lower respiratory tract infections (LRTIs). The results of those trials have been such that the method has been approved by the FDA for treating sepsis in LRTIs. This trial set out to test this method in the setting of various causes of infection, as well as its effect on the development of infections by resistant organisms.

PATIENTS: Those with sepsis and LRTIs, acute pyelonephritis, or primary bloodstream infections

INTERVENTION: PCT-guided termination of antibiotics

CONTROL: Discontinuation of antibiotics by the standard of care (SOC)

OUTCOME: Rate of infection-associated adverse events

Secondary Outcomes: Time to new infection, length of antibiotic treatment, mortality, and cost of hospitalization

METHODS (BRIEF DESCRIPTION):

- Procalcitonin group: Procalcitonin drawn on days one and five with termination of antibiotics if it had decreased more than 80% or was <0.5 µg/L.
- The control group was managed with SOC "according to international guidelines".
- Stool samples were collected from all participants at days 0, 7, 28, and 180 to identify the presence of *C. difficile* and multidrug-resistant organism (MDRO) colonization.
- The primary outcome was measured by the time it took to identify a new case of *C. difficile*, a new case of MDRO infection, or death with either.
- The secondary outcomes were measured by the time it took to develop a new infection, length of antibiotic treatment, mortality at days 28 and 180, and cost of each participant's hospitalization.
- Data was compiled by researchers that were blinded to the participants' group.

INTERVENTION (# IN THE GROUP): 125

COMPARISON (# IN THE GROUP): 131

FOLLOW UP PERIOD: 180 days from the start of antibiotics

RESULTS:

Primary Outcome –

- The procalcitonin group experienced a decrease in infection-associated adverse events compared to the SOC group (HR 0.4; 95% CI, 0.2–0.9).
- The SOC group had a higher risk for *C. difficile* and MDRO infections in those colonized with either compared to the procalcitonin group (OR 13; 95% CI, 3.7–43 for day 7; and OR 11; 95% CI, 3.6–33 for day 28)

Secondary Outcomes –

- The procalcitonin group had reduced 28-day mortality (HR 0.5; 95% CI, 0.3–0.9) and after 28 days (HR 0.51; 95% CI, 0.29–0.89) compared to the SOC group.
- The procalcitonin group had a shorter length of antibiotic treatment compared to the SOC group (5 days vs 10 days; $P<.001$), regardless of the infection in question.
- The procalcitonin group had a decreased incidence of diarrhea (OR 0.4; 95% CI, 0.2–0.7) and acute kidney injury (OR 0.4; 95% CI, 0.2–0.8) compared to the SOC group.

LIMITATIONS:

- Limited stool sampling between days 28 and 180.
- Generalizability as the trial was performed in a country with high antimicrobial use and resistance.
- Participants did not require treatment in the intensive care unit.
- The authors failed to document the length of time before a new infection.

Ana Leon-Arango, MD
Texas A&M University FMRP
Bryan, TX

Does Amantadine Improve Cognitive Function After a Nonpenetrating Traumatic Brain Injury?

Amantadine Did Not Positively Impact Cognition in Chronic Traumatic Brain Injury: A Multi-Site, Randomized, Controlled Trial

Hammond FM, Sherer M, Malec JF, et al. Amantadine Did Not Positively Impact Cognition in Chronic Traumatic Brain Injury: A Multi-Site, Randomized, Controlled Trial. *J Neurotrauma*. 2018; 35(19):2298–2305. doi:10.1089/neu.2018.576

KEY TAKEAWAY: Amantadine for chronic TBI does not benefit overall cognition but may have a small transient negative impact on cognitive functioning during the first month of treatment.

STUDY DESIGN: Randomized double blinded, multisite, placebo controlled parallel study

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Long-term cognitive impairment has been reported in up to 65% of individuals with moderate to severe traumatic brain injury (TBI). Amantadine is a common pharmacological agent to improve cognitive dysfunction after TBI. Several small studies suggest some cognitive benefit from amantadine. There is a need for a thorough scientific evaluation of amantadine's effect on cognition.

PATIENTS: 16- to 75-year-olds with TBI

INTERVENTION: Amantadine 100 mg

CONTROL: Placebo

OUTCOME: Cognitive function

METHODS (BRIEF DESCRIPTION):

- Participants with nonpenetrating TBI at least six months prior to enrollment were recruited.
- TBI was verified by records and clinician interview using certain criteria.
- 119 participants were selected with significant cognitive impairment indicated by two or more cognitive test scores at least one standard deviation below normal.
    - Exclusion Criteria: Unable to communicate, history of neurological disorder, using typical neurolepic agents or MAOI.
- Participants were given either amantadine 100 mg BID (morning and noon) vs placebo and were measured at 0, 28, and 60 days.
- The outcomes were measured using neuropsychological tests including the Overall Composite (GCI), Learning memory index (LMI), and Attention/Processing speed index (APSI) and were converted to standardized scores.
    - LMI: California Verbal Learning test that includes free and delayed cue recall tests.
    - APSI: Comprised of processing speed, trail making test, and controlled oral word association test.
    - GCI: Overall composite that is comprised of combination of both LMI and APSI tests.
- Intention to treat analysis was used.

INTERVENTION (# IN THE GROUP): 59

COMPARISON (# IN THE GROUP): 60

FOLLOW UP PERIOD: 60 days

RESULTS:

- At day 28, the placebo group had a greater improvement in cognitive performance from baseline in GCI compared to the amantadine group (6.2 percentiles; 95% CI, 2.3–10).
    - Similar results were found in LMI (10 percentiles; 95% CI, 4.0–16).
- At day 60, both GCI and LMI were similar between the groups.
- There was no difference in APSI between groups.

LIMITATIONS:

- This study did not focus on a particular level of cognitive impairment.
- Short follow up period.
- The population studied had an average of six years post injury with significant heterogeneity from initial trauma.
- Previous studies used different dosage ranging between 200–400 mg/day.

Tarekh Baosman, MD
HCA Virginia Health System – LewisGale Medical Center
Roanoke, VA

Are Platelet-Rich Injections an Effective Treatment for Chronic Midportion Achilles Tendinopathy?

Effect of Platelet-Rich Plasma Injection vs Sham Injection on Tendon Dysfunction in Patients with Chronic Midportion Achilles Tendinopathy

Kearney RS, Ji C, Warwick J, et al. Effect of Platelet-Rich Plasma Injection vs Sham Injection on Tendon Dysfunction in Patients with Chronic Midportion Achilles Tendinopathy: A Randomized Clinical Trial. *JAMA*. 2021; 326(2):137–144. doi:10.1001/jama.2021.6986

KEY TAKEAWAY: Platelet-rich plasma injections are not an effective treatment for chronic midportion Achilles tendinopathy.

STUDY DESIGN: Participant-blinded, multicenter randomized clinical trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Platelet-rich plasma (PRP) injections are marketed to treat chronic midportion Achilles tendinopathy by using growth factors from the patient's whole blood to promote tendon repair at sites of chronic degeneration. Although there are organizations that support this therapy as a treatment option, there are limited randomized clinical trials to support its effectiveness.

PATIENTS: Those with midportion Achilles tendon pain >3 months

INTERVENTION: Platelet-rich plasma injections of Achilles tendon

CONTROL: One dry injection inserted into the skin (non-tendon)

OUTCOME: Severity of chronic Achilles tendinopathy

METHODS (BRIEF DESCRIPTION):

- The patients in this trial were 18 years or older with midportion Achilles tendon pain for more than three months. Ultrasound, MRI, or both were used to confirm tendinopathy.
- The intervention group had PRP injected into the Achilles' tendon, with five total injections into the tendon through one skin site.
- The control group had one dry injection into the skin, not the tendon, for 10 seconds.
- Patients with chronic midportion Achilles tendinopathy were referred to the trial, and based on meeting eligibility criteria, were randomized in a 1:1 ratio to receive the PRP injection or the sham injection. All participants had whole blood withdrawn.
    - The PRP group had whole-blood centrifugation performed and then inserted into the tendon.
    - For the sham group, their blood was discarded, and they waited 30 minutes before receiving the injection.
    - Both groups' participants laid in the prone position, then received local anesthesia with 5 mL of 2% lidocaine and either PRP or dry injection was performed.
- Outcomes were measured using the VISA-A, 5-level Euroqol Questionnaire, and the Visual Analog Scale.

INTERVENTION (# IN THE GROUP): 121

COMPARISON (# IN THE GROUP): 119

FOLLOW UP PERIOD: 6 months

RESULTS: There was no significant difference between the PRP group and placebo group at six months (MD –2.7; 95% CI, –8.8 to 3.3)

LIMITATIONS:

- No imaging was utilized to confirm placement of the PRP into the tendinopathic region of the Achilles' tendon.
- 77 participants in the study received other additional treatments during the study.
- Each PRP injection was not individually assessed.

Calli Fry, DO
Texas A&M FMRP
Bryan, TX

Is Lower Blood Pressure Still Better? Revisiting SPRINT

Patient Selection for Intensive Blood Pressure Management Based on Benefit and Adverse Events

Bress AP, Greene T, Derington CG, et al. Patient Selection for Intensive Blood Pressure Management Based on Benefit and Adverse Events. *J Am Coll Cardiol*. 2021; 77(16):1977–1990. doi:10.1016/j.jacc.2021.02.058

KEY TAKEAWAY: In patients with the highest CVD risk, there was no statistically significant benefit from intensive systolic blood pressure treatment.

STUDY DESIGN: A secondary analysis of a multi-center randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: It is difficult to determine baseline cardiovascular risk as every patient is different. It is known that intensive blood pressure goals can reduce the risk of cardiovascular events and all-cause mortality. The purpose of this secondary analysis was to evaluate how baseline cardiovascular risk can influence the benefit of the intensive blood pressure treatment.

PATIENTS: Older adults at increased risk of atherosclerotic cardiovascular disease (ASCVD)

INTERVENTION: Intensive blood pressure lowering

CONTROL: Standard blood pressure lowering

OUTCOME: Cardiovascular disease (CVD) outcomes, all-cause mortality

Secondary Outcomes: Benefit of treatment, adverse events

METHODS (BRIEF DESCRIPTION):

- Patients were at least 50 years old with systolic blood pressure (SBP) 130–180 mmHg who had at least a 15% increased ASCVD risk.
  - Exclusion Criteria: History of diabetes, stroke, heart failure, eGFR <20.
- Patients were randomized to either intensive blood pressure lowering to goal (SBP <120) or standard blood pressure lowering to goal (SBP <130).
- Overall absolute risk for CVD outcomes and all-cause mortality was predicted using a modified cox regression model.
- C-for-benefit ratio (which assesses a prediction model's treatment benefit) was calculated to assess if patients with higher baseline risk had increased benefit of intensive treatment.
  - C-for-benefit ratio closer to 1 equates more benefit.
- Spearman's correlation coefficient (which determines if two variables have a direct or indirect relationship) was calculated to evaluate the relationship between treatment benefit and treatment adverse events. A value close to 1 is a direct relationship while a value close to –1 is an indirect relationship.

INTERVENTION (# IN THE GROUP): 4,429

COMPARISON (# IN THE GROUP): 4,399

FOLLOW UP PERIOD: 3.3 years

RESULTS:

Primary Outcomes:

- The intensive BP lowering group did not differ compared to the standard BP group in the following areas:
  - CVD events (255 vs 245, respectively; *P*=.48)
  - All-cause deaths (157 vs 206, respectively; *P*=.18)
  - Adverse effects (312 vs 169, respectively; *P*=.68)

Secondary Outcomes:

- Patients with a higher ASCVD risk had greater benefit in absolute risk reduction for all-cause mortality from intensive treatment with regards to absolute risk reduction (C-for-benefit ratio 0.55).
- Patients with more intensive treatment had more adverse events, directly correlating to increased CVD outcomes and all-cause mortality (Spearman's correlation coefficient of 0.72 and 0.76, respectively).

LIMITATIONS:

- Heart failure was not included in the pooled cohort equation, thus requiring the creation of a new CVD risk predicting tool.

Adriana Carpenter, DO
Nellis AFB FMR
Nellis AFB, CA

Fetal Growth Restriction and School Performance: Is There a Connection?

Association Between Iatrogenic Delivery for Suspected Fetal Growth Restriction and Childhood School Outcomes

Selvaratnam RJ, Wallace EM, Wolfe R, Anderson PJ, Davey M-A. Association between iatrogenic delivery for suspected fetal growth restriction and childhood school outcomes. *JAMA*. 2021; 326(2):145–153.

KEY TAKEAWAY: Infants born with severe small for gestational age (SGA) that were iatrogenically delivered for suspected fetal growth restriction (FGR) had poorer developmental and educational outcomes compared with infants with severe SGA not suspected of FGR.

STUDY DESIGN: Retrospective whole population cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: FGR is the largest contributor to late pregnancy stillbirth. Therefore, the timely delivery of a suspected FGR fetus is an important decision, one that requires weighing the risk between a desire to prevent stillbirth and the risks of prematurity. Early delivery has been associated with poorer childhood neurodevelopmental and educational outcomes as well as an increased risk of having worse neonatal outcomes. Complicating the decision further, many infants suspected of having FGR have normal growth. Though improving the detection of FGR may prevent the likelihood of stillbirth, it may also inadvertently cause harm for an increasing number of healthy infants.

PATIENTS: Infants suspected of FGR

INTERVENTION: Iatrogenic delivery of infants with severe SGA due to suspected FGR

CONTROL: Infants with severe SGA not suspected of having FGR

OUTCOME: Childhood developmental and educational outcomes

METHODS (BRIEF DESCRIPTION):

- All singleton live births at ≥32 weeks' gestation born in Victoria, Australia 1/1/2003–12/31/2013 were included in this study.
  - Infants with missing gestation, birth weight, birth status, and labor type were excluded.
- Participants were followed until 7th grade or until 2019.
- The primary developmental outcome was defined as a child that scored in the bottom 10th percentile on a minimum of 2 of the 5 Australian Early Development Census domains.
- The coprimary educational outcome was a child who scored below the National Minimum Standard on a minimum of 2 of the 5 National Assessment Programs.
- GA was defined as birth weight <10% and severe SGA was <3%.
- Infants were classified as iatrogenically delivered for suspected FGR if they were delivered by induction or pre-labor cesarean delivery and the ICD-10 code O365 (suspected poor fetal growth) was listed as an indication for delivery.
- Three groups of severe SGA were compared: infants with severe SGA and iatrogenically delivered for suspected FGR, infants with severe SGA suspected of having FGR, and not iatrogenically delivered and infants with severe SGA not suspected of having FGR.

INTERVENTION (# IN THE GROUP): 693

COMPARISON (# IN THE GROUP): 435

FOLLOW UP PERIOD: 7th grade or 2019

RESULTS:

- Infants with severe SGA delivered for suspected FGR had increased odds of poor developmental and educational outcomes compared with infants with severe SGA not suspected of having FGR (OR 1.4; 95% CI, 1.1–1.7).
  - Grade 3: OR 1.3; 95% CI, 1.1–1.6
  - Grade 5: OR 1.3; 95% CI, 1.1–1.5
  - Grade 7: OR 1.3; 95% CI, 1.1–1.7
- There was no difference in developmental outcomes between infants with normal growth (birth weight ≥10th percentile) delivered for suspected FGR and those not suspected of having FGR (OR 1.2; 95% CI, 0.9–1.4).

LIMITATIONS:

- The study did not examine other factors that contribute to academic success.
- Victorian Perinatal Data Collection prior to 2009 did not include data on smoking during pregnancy, maternal BMI, and breastfeeding status. Maternal exposure to alcohol and substance use in pregnancy was not included at all.

- Fetal biometry and doppler studies were not recorded to help differentiate between pathologically and physiologically small infants.
- Underlying etiology for FGR, genetic abnormalities, functional impairments, and disability were unknown.

Carson Klein, MD
Texas A&M FMR
Bryan, TX

Osteopathic Manipulative Treatment Can Reduce Low Back Pain-Related Activity Limitations, but What About Subacute and Chronic Symptoms?

Effect of Osteopathic Manipulative Treatment vs Sham Treatment on Activity Limitations in Patients with Nonspecific Subacute and Chronic Low Back Pain: A Randomized Clinical Trial

Nguyen C, Boutron I, Zegarra-Parodi R, et al. Effect of Osteopathic Manipulative Treatment vs Sham Treatment on Activity Limitations in Patients with Nonspecific Subacute and Chronic Low Back Pain: A Randomized Clinical Trial. *JAMA Intern Med*. 2021 Mar 15. doi: 10.1001/jamainternmed.2021.0005.

KEY TAKEAWAY: Compared to sham OMT, standard OMT has a small statistical effect of uncertain clinical importance on the reduction of nonspecific subacute or chronic lower back pain-related activity limitations at three months and at 12 months.

STUDY DESIGN: Prospective, single-blind, parallel-group RCT

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Osteopathic manipulative treatment (OMT) is a commonly used modality to treat low back pain. While OMT has been shown to decrease acute low back pain, substantial evidence for use of OMT in subacute and chronic low back pain (LBP) is lacking.

PATIENTS: Adults with nonspecific subacute or chronic LBP

INTERVENTION: Treatment OMT

CONTROL: Sham OMT

OUTCOME: LBP specific activity limitations

Secondary Outcomes: Reduction in LBP-specific activity limitations; changes in back pain and health-related quality of life (QOL); number and duration of sick leaves; number of LBP episodes at one year; use of analgesics and NSAIDs at three months and one year

METHODS (BRIEF DESCRIPTION):

- Participants were largely recruited from an inpatient and outpatient pool in the physical medicine and rehabilitation department of a French tertiary care medical center.
  - Median age: 50 years old
- Trial investigators and osteopathic practitioners were not blinded.
- Analysts and participants were blinded.
- Participants were randomly allocated in a 1:1 ratio to either standard OMT or sham OMT, both groups received six 45-minute sessions.
- Sham treatment was defined as light touch: "an a priori inert procedure used to reduce therapeutic aspect of the touch by the osteopathic practitioner."
- Treatment sessions were audio recorded to monitor practitioner speech patterns and subsequently analyzed for verbal behavior, attitude, and speech content.
- LBP specific activity limitations were assessed using a self-administered Quebec Back Pain Disability Index at three months follow up (0=no limitations; 100=maximum limitations).
- Secondary outcomes were assessed using the QBPDI at 12 months as well as via the Medical Outcomes Short Study Form 12 at 3 months and 12 months, self-reported sick leaves at 12 months, and self-reported analgesic and NSAID use at 3 and 12 months.

INTERVENTION (# IN THE GROUP): 200

COMPARISON (# IN THE GROUP): 200

FOLLOW UP PERIOD: 3 months and 12 months

RESULTS:

Primary Outcomes –

- Standard OMT decreased LBP specific activity limitations more than sham OMT at three months (MD –3.4; 95% CI, –6.0 to –0.7).
  - The standard OMT group's mean activity limitations decreased from baseline to three months (32 vs 25; MD –4.7; 95% CI, –6.6 to –2.8).
  - The sham OMT group's mean activity limitations did not change from baseline to three months (27 vs 26; MD –1.3; 95% CI, –3.3 to 0.6).

Secondary Outcomes –

- Standard OMT decreased LBP specific activity limitations more than sham OMT at 12 months (MD –4.3; 95% CI, –7.6 to –1.0).
- There were no differences in lower back pain, health related QOL, number and duration of sick leave, number of LBP episodes at one year, or the use of analgesics or NSAIDs.

LIMITATIONS:

- Standard OMT by osteopathic providers who were neither physicians nor physiotherapists (approximately 60% of French osteopathic providers are not trained in medicine or physiotherapy).

- Single center trial.
- Participants with missing outcome data were assumed to have similar outcomes as similar participants who were not missing outcome data.
- High drop-out rate.

Aaron Magaña, DO, MS
Advocate Illinois Masonic Family Medicine Program
Chicago, IL

Barriers and Facilitators that Affect Successful Case Management in Primary Care

Understanding Barriers to and Facilitators of Case Management in Primary Care: A Systematic Review and Thematic Synthesis

Teper MH, Vedel I, Yang XQ, Margo-Dermer E, Hudon C. Understanding Barriers to and Facilitators of Case Management in Primary Care: A Systematic Review and Thematic Synthesis. *Ann Fam Med*. 2020; 18(4):355-363. doi: 10.1370/afm.2555.

KEY TAKEAWAY: There are several important key barriers and facilitators of case management, and the presence of and the interactions among these factors determine whether case management will be successfully implemented in the primary care setting.

STUDY DESIGN: Systematic review and thematic synthesis of qualitative findings

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: Patients with complex needs in primary care, such as those with multiple chronic conditions, which may or may not be compounded by mental health illnesses and social vulnerability, not only are high expenditures of health care resources, but often receive poor care coordination and chronic disease management. Case management is a potential beneficial tool that can be utilized in the primary care setting to help optimize care management for these patients. Despite this fact, it was found that there are multiple barriers to effective, sustainable care management.

PATIENTS: Those with "complex medical problems" in the outpatient primary care setting

INTERVENTION: Care management

CONTROL: None

OUTCOME: Barriers and facilitators that affect case management in primary care

METHODS (BRIEF DESCRIPTION):

- Three electronic databases were utilized to search for qualitative studies pertaining to barriers and facilitators of care management in the primary care setting.
- The study utilized the Standards for Reporting Qualitative Research (SRQR) tool to assess the quality of the studies.
- The barriers and facilitators were discussed by these studies were analyzed and synthesized.
- A framework of these factors was then used to create a framework that organizes these barriers based on how they influence case management.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not applicable

FOLLOW UP PERIOD: Not applicable

RESULTS:

- Important barriers and facilitators of case management:
  - Structural factors such as family context
  - Policy and available resources
  - Physician buy-in and understanding of case manager role
- Intermediate factors:
  - Training in technology
  - Relationships with patients
  - Time pressure and workload
  - Relationship building
  - Autonomy of case manager
  - Team communication practices
- Fundamental factors:
  - Knowledge (knowing what to do)
  - Capacity (having the ability to do it)
  - Conducting case management in primary care

LIMITATIONS:

- The search was limited to the three databases utilized, so there is a possibility that relevant articles may be excluded, and thus relevant information may be excluded.
- Publication bias.
- Generalization of the barriers and facilitators can be a strength but also a limitation.

Nhi-Kieu Nguyen, DO
Northeast Georgia Medical Center FMRP
Gainesville, GA

Does Empathy from PCPs Affect Mortality Among Type II Diabetics?

Association between Primary Care Practitioner Empathy and Risk of Cardiovascular Events and All-Cause Mortality Among Patients with Type-2 Diabetes: A Population-Based Prospective Cohort Study

Dambha-Miller H, Feldman AL, Kinmonth AL, Griffin SJ. Association Between Primary Care Practitioner Empathy and Risk of Cardiovascular Events and All-Cause Mortality Among Patients with Type 2 Diabetes: A Population-Based Prospective Cohort Study. *Ann Fam Med.* 2019; 17(4):311-318. doi: 10.1370/afm.2421.

KEY TAKEAWAY: Patients with type II diabetes reporting higher levels of practitioner empathy in the first 12 months of diagnosis did not experience a lower risk of cardiovascular events over 10 years.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: It seems intuitive that patients are more likely to have better outcomes from following the recommendations of physicians who better empathize with them. The relationship between patient perceptions of primary care provider empathy and cardiovascular and all-cause mortality among diabetic patients is unknown. Prior studies have had shorter follow-up periods.

PATIENTS: Adults in the United Kingdom with type II diabetes

INTERVENTION: Higher perceived empathy from providers (tertile 1)

CONTROL: Lower perceived empathy from providers (tertiles 2 and 3)

OUTCOME: Composite of myocardial infarction, stroke, revascularization, non-traumatic amputation, and fatal cardiovascular events

Secondary Outcome: All-cause mortality

METHODS (BRIEF DESCRIPTION):

- Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care (ADDITION) was used to cluster-randomize 867 individuals with type II diabetes. Of all the participants, 60% were male, 97% were white, and mean age at baseline was 61.
- 628 individuals completed the Consultation and Relational Empathy (CARE) questionnaire 12 months later. The questionnaire consisted of 10 questions which asked questions regarding patients' perception of received care and empathy from physicians and nurses. Scores ranged from 0 to 50 with higher scores corresponding to higher perceived empathy.
- The scores on the CARE questionnaire were organized into three tertiles: Tertile 1 comprising of scores <37, Tertile 2 comprising of scores 38-46, and Tertile 3 comprising of scores >46.
- Cardiovascular and all-cause mortality were tracked over the next 10 years through searches of general practitioners' records, national registries, office of national statistics, and hospital records.

INTERVENTION (# IN THE GROUP): 206

COMPARISON (# IN THE GROUP): 422

FOLLOW UP PERIOD: 10 years

RESULTS:

- Higher perceived empathy did not lead to statistically significant differences between cardiovascular mortality comparing tertile 1 and tertile 2 (multivariable HR 0.64; 95% CI, 0.35–1.1) or when comparing tertile 1 and tertile 3 (multivariable HR 0.66; 95% CI, 0.38–1.2).
- Higher perceived empathy did not lead to statistically significant differences in all-cause mortality comparing tertile 1 and tertile 2 (multivariable HR 0.49; 95% CI, 0.27–0.88) or when comparing tertile 1 and tertile 3 (multivariable HR 0.60; 95% CI, 0.35–1.0).

LIMITATIONS:

- The study is based on a single measure taken at a single time although outcomes were tracked over 10 years.
- Patients' perception of empathy may not be entirely a reflection of the physician's skills.
- Predominance of one group that identified as white may have resulted in the skewing of the results which may decrease external validity.

Viraj S Sidhu, MD
Central Michigan University FMRP
Saginaw, MI