Evidence vs. Anecdote in Foot and Ankle Surgery

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Evidence: The available body of facts suggesting a belief is true or valid.
Anecdote: A short, amusing or interesting story that need be neither true nor valid.

Diagnosis and treatment decisions are often based on sketchy information passed down through the years; eventually becoming dogma; gradually assuming the mantle of fact masquerading as knowledge. We must revisit some of these established treatment trends to determine if there is an evidence base to support their use.

Table 1: Levels of Evidence in Medicine

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of Study</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Randomised Clinical Trials (RCT)</td>
</tr>
<tr>
<td>2</td>
<td>Lower quality RCT</td>
</tr>
<tr>
<td>3</td>
<td>Case controlled Studies</td>
</tr>
<tr>
<td>4</td>
<td>Case Series</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

The quality of the information obtained influences the level of evidence ranking. Quality indicators include the type of study, quality of the study design, percent follow up, statistical methods and enrollment criteria utilised for the clinical trial (Table 2).

Foot and ankle research has primarily been Level 4 retrospective cases series. A recent publication by Hunt and Hurwit (2013) reviewed our foot and ankle literature to assess the level of evidence over a 9-10 year time period. They found 70% Level 4 studies, 12% Level 3, 9% Level 2 and only 9% Level 1 studies. This was actually an improvement over earlier papers looking at the level of evidence in foot and ankle literature. Although current publications record the level of evidence, older literature did not. Here we will look back on some well held principles of foot and ankle care from older literature to determine whether or not these “peer reviewed” papers were in fact based on evidence or anecdote.

Table 2: Quality indicators for Clinical Research in Medicine *

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Quality of the Study Design</th>
<th>% of Patient Follow up</th>
<th>Statistical methods</th>
<th>Enrollment criteria</th>
</tr>
</thead>
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The rigour of these quality measures impacts the level of evidence assigned to the research.

This article is based on the Naughton Dunn Lecture given by Judith Baumhauer at the BOA Annual Congress in Birmingham 2013.
The index citation tool on the Web of Science was used to provide a listing of the most highly cited peer reviewed papers in the world literature cross referenced for foot and ankle over the last 30 years. Identifying a highly cited paper and assessing whether or not the science behind that paper used quality research principles would give us some insight as to whether or not we are perpetuating dogma or if we are truly using high level evidence.

"The rupture of posterior tibial tendon causing flat foot - surgical-treatment" authored by Roger Mann and Francesca Thompson in 1985 was cited 213 times. In the conclusions that are drawn from the evidence of the article: "Isolated FDL transfer to the navicular arrests the flat foot deformity, relieves pain and restores inversion power of the hindfoot. It is therefore a well-meaning anecdote. There are numerous case studies available in the foot and ankle literature. These case studies do not have a level of evidence to support universal adoption of the suggested treatment as in the use of an isolated FDL transfer to navicular however; they do provide information that can lead to further study. Pinney published a symposium on evidence based medicine: "What is it and how should it be used?". A section looked at case series (level 4) and case reports (level 5). These published Level 4 and 5 studies allow clinicians and researchers to be exposed to new ideas which may be the stepping stones for more advanced study. Friedman, JAMA 1999 commented about Level 4 and 5 studies. "These lower level studies provide detailed observations and descriptions of new diseases or conditions. They also provide pilot study data for future power analyses and aid in study design. These Level 4 and 5 studies also may have a quick turn around on time sensitive issues opposed to Level 1 and 2 studies which often can take years to get the available data and conclusions into the literature. These case series and case reports may be the only options for orphan or very rare conditions and they also allow us to detect drug side effects in an expedient manner."

Hoffman et al published an article on the negative implications of case series and case reports. They looked into the percentage of case series and case reports that have been used as stepping stones for Level 1 or 2 studies. They highlighted that most new ideas, from these lower level evidence papers, are not substantiated with more rigorous research. They argue that the case series and case reports contain misleading data and conclusions with small subject numbers and wide variation. The data is often qualitative and not quantitative and it lacks validated outcome measures as we saw with the FDL to navicular paper. They summarise their conclusions with a comment "does more harm than good by focusing on the bizarre."

Despite the negative comments made by Hoffman and his colleagues, there are historic examples of Level 4 and 5, evidence that have made great contributions to the advancement of patient care. In the 1980’s, Drs. Conant and Volberg recognised a unique tumor, Kaposi’s sarcoma in eight homosexual males. It is their recognition of this link that led to the recognition of AIDS and HIV virus transmission. In 1952, Dr. Jonas Salk produced a polio vaccine consisting of a dead injectable virus, and in 1957 Albert Sabin, M.D. produced an attenuated vaccine tested in 19 children that could be taken orally. Salk was credited with the eradication of polio in the United States while Sabin’s oral vaccine has been utilised throughout the world. These Level 4 case series changed care around the world.

Mr. Naughton Dunn, M.D. recognised the importance of case series and the re-evaluation of his patients to improve patient care. In his presidential address in 1928 he stated, “If we refer to a modern textbook on orthopaedic surgery we find that all the principles on which we rely for the treatment of infantile paralysis are recorded, so that I have nothing new to offer. My only reason for selecting this subject for discussion is that so many alternative treatments are advised that a frank review of these and the results of our own practice and experience may be helpful”. Mr. Dunn recognised that anecdotal information had been perpetuated by repetition. He recognised the need for a frank assessment of these treatments. Mr. Dunn published a case series entitled “Calcaneal cavus and its treatment” in 1919. He looked at a wedge resection of the midfoot to correct a cavus foot along with a soft tissue release of the Achilles. He provided pre- and post-operative radiographs and clinical photographs of his patients. This type of surgery and treatment is still utilised today.

In summary, the rupture of the posterior tibial tendon causing flat foot – surgical – treatment by Drs. Mann and Thompson was a meaningful case series but not critical evidence. It led to a number of higher level evidence studies with control groups comparing different treatment options for posterior tibial tendon dysfunction. It did advance the science.
The fifteenth most commonly cited Web of Science article in foot and ankle was out of JAMA entitled “Preventing foot ulcers in patients with diabetes”[15]. The conclusions are “substantial evidence supports screening all patients with diabetes to identify those at risk for foot ulceration. These patients might benefit from certain prophylactic interventions including patient education, prescription foot wear, intensive podiatric care, and evaluation for surgical interventions.” If we look at the quality research indicators, this paper was in fact a Level 1 systematic review. The authors looked at 165 articles, 22 of which were randomised controlled trials. The primary outcome measures utilised in the study included ulceration or amputation with or without intervention. They reviewed the factors resulting in diabetic foot ulceration including peripheral neuropathy, vascular insufficiency, increased plantar pressures, poor glucose control and smoking and examined interventions aimed at decreasing ulceration or amputation. The support for these treatments might actually be regarded as anecdote rather than evidence. A better summary that is supported by the evidence would have included only routine foot exams.

Mr. Naughton Dunn recognised the importance of clinical outcomes in assessing our patients and stated in a paper published in 1922 “Orthopaedic surgery is so closely associated with function that perhaps in no other branch of surgery is the patient in a better position to judge of the practical success or failure resulting from any operative procedure”[17]. Naughton Dunn was certainly ahead of his time in recognising the importance of patient derived outcomes.

The number one citation from the Web of Science was a paper entitled “Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes”[16]. This particular paper has been cited over 1,200 times. The summary statement from this article is “Four rating systems were developed by the American Orthopaedic Foot and Ankle Society to provide a standard method of reporting clinical status of the ankle and foot. The systems incorporate both subjective and objective >>

### Hallux Metatarsophalangeal-Interphalangeal Scale (100 points total)

#### Pain (40 points)

- None 40
- Mild, occasional 30
- Moderate, daily 20
- Severe, almost always present 0

#### Function (45 points)

- Activity Limitations
  - No limitations 10
  - No limitation to daily activities, such as employment responsibilities, limitation of recreational activities 7
  - Limited daily and recreational activities 4
  - Severe limitation of daily and recreational activities 0

- Footwear requirements
  - Fashionable, conventional shoes, no insert required 10
  - Comfort footwear, shoe insert 5
  - Modified shoe or brace 0

- MTP joint motion (dorsiflexion plus plantarflexion)
  - Normal or mild restriction (75° or more) 10
  - Moderate restriction (30°-74°) 5
  - Severe restriction (less than 30°) 0

- IP joint motion (plantarflexion)
  - No restriction 5
  - Severe restriction (less than 10°) 0

- MTP-IP stability (all directions)
  - Stable 5
  - Definitely unstable or able to dislocate 0

- Callus related to hallux MTP-IP
  - No callus or asymptomatic callus 5
  - Callus, symptomatic 0

#### Alignment (15 points)

- Good, hallux well-aligned 15
- Fair, some degree of hallux malalignment observed, no symptoms 8
- Poor, obvious symptomatic malalignment 0
factors into numerical scales to describe function, alignment and pain.” An example of the hallux metatarsophalangeal-interphalangeal scale is provided in Table 3. From: Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994 Jul;15(7):349-53.

These clinical rating scales are anatomic outcomes instruments that are clinician derived and administered. There are four anatomic scales and each includes the items of pain, function and alignment in a point allocation system that totals 100 points. It takes about five minutes to complete.

Despite high numbers of citations for this paper, many subsequent publications have raised questions over the validity and reliability of the clinical rating scales [18-20]. This paper, the number one cited foot and ankle paper identified by the Web of Science, is anecdotal and should not be used? Foreward. Foot Ankle Int. 2010 Nov 31(11):1037-9.

With the sun setting on the AOFAS clinical scoring systems, comes an opportunity to re-evaluate what type of outcomes measures might be appropriate for foot and ankle. The PROMIS is a Patient Reported Outcomes Measurement System that has been developed in collaboration with Northwestern University in Chicago, IL and National Institute of Health [21,22]. It allows healthcare providers to assess patient reported outcomes through the utilisation of a technique called item response theory (IRT) and computer adaptive testing (CAT). Through the PROMIS system, patients are asked questions in a variety of different domains including lower extremity physical functioning. The American Orthopaedic Foot and Ankle Society is currently organising pilot projects to look at the feasibility of the PROMIS physical functioning CAT tool [23,24]. First steps included gathering data from 10 academic centres to optimise the data collection and the utilisation process. With the next step PROMIS will be rolled out into a sample of private practices that often do not have the infrastructure for outcomes assessment. Additionally, the Society has been examining the bank of questions that are currently utilised in the lower extremity physical functioning domain and comparing it to other legacy scales such as the clinical rating scales.

In summary, evidence is really based on quality research. There are quality measures that can be used to evaluate publications. We need to be critical in the assessment of research that influences the treatment of patients to determine whether or not the foundation of any research is evidence or anecdote. All levels of evidence have value; however, taking research directly to our patients needs a critical eye to avoid dogma.

References

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This includes the popular and thought-provoking Howard Steel Lecture by Mark Stevenson: ‘The Future ... and what to do about it’.