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## ***Data, Analysis, and Recommendations Are Questionable***

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The article by Arshi et al. addresses a timely subject. I support research to improve the efficacy of outpatient TKA, but this study has limitations in its analysis of data and recommendations. Firstly, this database is not known, and I have not seen previous meta searches published from it, so we must assume the data is well controlled. All meta-searches have inherent faults, which are present in this publication: clarity, relevance, and consistency [1].

With this study I have several concerns:

1. The first is the data clarity because no information is given on the definition of the diagnoses: Does this hospital system have a standard protocol for diagnosis of infection and DVT? The data were collected from diagnoses from billing records, which can be unreliable. If this is independent data from multiple hospitals with no standardized control, then the diagnosis of infection and DVT can vary from strict diagnostic criteria to subjective clinical diagnosis.
2. A second concern is the relevance of the data, assuming the billing codes are accurate. The authors should have identified red flags in this data. Outpatient surgery should have no correlation to non-infectious revision of components within one year. The authors should have identified whether these patients came from the same hospital or same area. This complication doesn't fit with the time of discharge. Likewise, increased manipulations can be technical ("too tight a knee") or patellofemoral errors. Were the increased manipulations from the same hospitals as the aseptic revisions, or were there any notations as to the cause of manipulation?
3. Also, increased DVT doesn't correlate to the day of discharge. All other studies (including the one by Basques et al. that precedes this article in the same *JBJS* issue) have reduced DVT because patients are up and active. We have done outpatient THR since 2005 [2], and have had only one DVT in 12 years in these

patients. DVT is higher in TKR patients, but this needs further investigation because it is an outlier.

4. The discussion lacks insight into outpatient knee replacement surgery. None of the attending surgeons listed as authors of this article are knee replacement surgeons, and I suspect none have experience with this treatment. If the authors want to do a meta-search as a research project the contribution could be worthwhile, but they should at least get some consultation on analysis of data and recommendations. This study is listed from Keck Medical Center, where I and Paul Gilbert are the only surgeons who do outpatient total joints, and neither of us was consulted. This helps explain why the comments on antibiotic administration are not relevant, because there is no data that correlates the length of antibiotic administration to the incidence of infection in the published outpatient studies of hip and knee replacement. For example, comments on 24 hours needed for antibiotic administration are not consistent with the data of surgeons who do outpatient surgery. In fact, there is no good data that says four doses are better than three. The problem with knees, and the reason infection is the #1 cause of readmission, is drainage that is not attended to. The current recommendation is to reoperate on a wound that drains for 5 days, and if the patient is an outpatient that can be assessed easily with pictures of the wound and the dressing sent by phone daily. There is not “limited ability” to track this. The occurrence of drainage is what the authors should have made the main focus of their discussion (instead they have only one sentence at the end of a long paragraph on antibiotics). Increase in infection is a real threat, and the reader needs to know the leading cause. In addition, does the database used for this study differentiate between I&D for drainage vs. that for infection? It is not defined in the methods, where only I&D is listed.

5. The recommendation for more physical therapy to prevent stiffness is also often the wrong recommendation. Experienced TKR surgeons know that therapists can be too aggressive, and patients leave their PT session sore, and this soreness limits movement with resulting stiffness. In fact, the better advice for patients with stiffness is to stop therapy until the soreness is controlled and then begin again with more gentle PT. This complication is another that has nothing to do with date of discharge. Stiffness leading to manipulation does not have anything to do with in-hospital PT time. If it is not a technical problem, then it is a consequence of poor follow-up, or too-aggressive PT or aggressive fibroblasts in some patients (and the diagnosis of RSD must also be thought of). Also, most surgeons doing outpatient surgery conduct a preoperative class for the patients that teaches them the complications to look for. Most surgeons also have a postoperative communication protocol to communicate with patients who go home the same day. Since this is a single hospital insurance program, were these educational and follow-up programs in place?

6. The assumption that DVT education is deficient because of discharge time makes no sense either. Even without a preoperative class, the DVT protocol for most surgeons doing outpatient surgery is aspirin – which is not complicated to explain. But assuming the education is bad, DVTs should not be higher because activity is the most important preventive – not chemoprophylaxis. No other outpatient surgery study reports increased DVTs, so the authors should have explored this inconsistent data.

7. The age of the patients (mean 70 to 74 years) is old for outpatient surgery. In this article almost all patients are older than 65, whereas in the Basques et al. article the patients are almost all below 65 years. There should be an explanation why these surgeons had their first experience with older patients. The recommendation to readers should be to begin their outpatient surgery experience with younger patients, and progress to older ones as their team gets experience, always taking into account the patient's medical health [3]. The reader deserves an explanation why the age was so much older than in other outpatient series.

This article has many of the deficiencies described by Jacofsky in his article [1], not the least of which is data that needs to be “cleaned” – detecting, diagnosing, and editing faulty data, especially regarding aseptic revisions, manipulations, and DVTs. Furthermore, the data is ambiguous for complications that just aren’t prevented by two days in the hospital vs. 12 hours. The analysis of the data is key to providing clinical recommendations augmented by “the voice of experience” of the authors. Unfortunately, this article provides neither, and the clinical recommendations are not accurate.

## References

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Conflict of Interest: None Declared

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## Article Author Response

14 February 2018

### *Article Author(s) to Letter Writer(s)*

#### **Article Authors Respond to Dr. Dorr**

We appreciate Dr. Dorr’s response to our manuscript, which highlights some of the limitations of analyses of claims databases. As noted in the Discussion, these limitations include the inability to identify more specific classifications of patient disease severity and perioperative protocols at specific hospitals.

However, his comments also highlight the utility of evaluating these large datasets. Specifically, the observational design allows for a broader analysis of outcomes that are not limited to a single institution or small group of specialized centers. Dr. Dorr comments on his own excellent results and some of the protocols he views as contributing to low rates of complications. Our study demonstrates that these outcomes are not yet uniformly observed when looking across a large dataset that includes all patients in the Humana administrative claims registry. The large dataset enables the identification of areas of potential concern where outcomes in broad practice do not match the outstanding results presented in the

reports of smaller studies that often come from high-volume, specialized practices. We can now work to disseminate best practices to decrease adverse outcomes and achieve consistent results from outpatient TKA more broadly.

In addressing Dr. Dorr's concerns, we would like to clarify the data source and methodology used in this study. PearlDiver is a healthcare database with over 20 million patient records across the United States in its database of Humana-insured patients. The data used is not derived from a single institution or hospital system and as such is less susceptible to provider bias. PearlDiver has been used extensively to answer research questions in more than 120 publications in leading orthopaedic and subspecialty journals (1-4). Earlier this year, *JBJS* published an article analogous to ours in design on ambulatory total shoulder arthroplasty using this source and similar methodology (5).

Any "big data" study is susceptible to errors in coding and limited data specificity that would limit the strength of its conclusions. Dr. Dorr suggests in points 1 and 2 of his letter that the definition of DVT and infection are not based on standardized criteria, as they are likely variable from individual providers in the de-identified database. To clarify, postoperative infections in this study were defined by whether or not reoperation was required based on CPT coding, and the definition was not reliant on the criteria of individual providers. Since reoperation with one-stage or two-stage revision is the standard of care for infected TKA, we believe this is an adequate method of detecting postoperative infections, and it is similar to the approach selected for current quality measures used by the Centers for Medicare and Medicaid Services. While there is again concern for data error, CPT coding is less susceptible to error than other forms of coding and is the basis for complication identification in nearly every "big data" source in surgery, including the well-validated American College of Surgeons NSQIP and the Nationwide Inpatient Sample databases (6). Similarly, DVTs and other postoperative medical complications were identified based on ICD coding by the insurer. Using CPT and ICD coding for the purposes of detecting complications has been well established in the literature using the PearlDiver database (1-5).

In points 3 through 6, Dr. Dorr also expresses some valid concerns about potential reasons for differences in septic and aseptic revisions, postoperative stiffness, and DVT rates among outpatients undergoing TKA. In our Discussion, we offered potential causes for these differences, such as variability in postoperative antibiotic administration, ability to monitor draining wounds, physical therapy and activity regimens, and DVT chemoprophylaxis in patients who undergo early discharge. Dr. Dorr is correct in that these explanations are speculative and there is no means of determining a true cause for higher complication

rates in an observational study design. However, that there is no attributable reason for a study finding does not mean that the finding is invalid or erroneous. Further clinical trials are needed to definitively identify which postoperative protocols will be effective in lowering rates of complications. We would like to point out that ours is not the only study to report higher rates of post-discharge complications on a population level (7). We also reiterate that while the absolute differences in complication rates between the two cohorts were small, they were statistically significant differences of between 22% and 65%. As such, we explicitly stated that “readers make their own judgment in the context of their own clinical practice and perioperative care regimen.” Indeed, these findings may not be clinically relevant in the high-volume centers that have reported uniformly excellent outcomes; however, they may reflect the feasibility of outpatient TKA in less-experienced centers and the United States as a whole.

Dr. Dorr’s observation in point 7 on the surprising age distribution of outpatient TKA in this study is one that we noted and discussed in our manuscript. In their 2017 article, Meneghini and colleagues discussed the importance of patient age and its correlation with their validated Outpatient Arthroplasty Risk Assessment score (8). Since the earliest reports on outpatient TKA, age has understandably been a primary factor in identifying ideal candidates because of higher incidence of perioperative morbidity (9). Unfortunately, we have no method of providing an explanation for why the de-identified surgeons performed outpatient TKA in an older patient population that may be at increased risk. However, the higher risk-adjusted incidence of postoperative complication noted in our study is independent of age based on multivariate regression. Clearly, this is a central issue that should be further examined in clinical studies to determine the ideal candidate for safe outpatient arthroplasty.

In summary, we agree that many of Dr. Dorr’s criticisms of “big data” study designs are important for thoughtful interpretation of the results. Despite these inherent limitations, our study across a large number of institutions highlights potential areas to focus on to improve the outcomes of outpatient total knee arthroplasty as it expands to become a more common practice. Further clinical trials will be critical in determining best practices for achieving this goal.

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