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Study Title Overstates Findings

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The article by Austin et al. is published at a critical time when cost-of-care issues and alternative models such as “bundled payments” are prominent in national health policy decision-making. Research suggesting that postoperative physical therapy (PT) is unnecessary can be used to support such payment models and individual payment decisions, so it is of utmost importance that researchers accurately depict the generalizability of their findings.

This article fails to demonstrate the authors’ chief claim that formal physical therapy is unnecessary for “most patients” after total hip arthroplasty (THA). The title and conclusions could be used to support misguided health policy and payment decisions. We base this opinion on the following points:

1. The title and conclusion create the impression that no formal physical therapy was received in the

unsupervised exercise group, when in fact all patients did receive formal PT intervention until their hospital discharge.

2. The conclusion that formal physical therapy is not required for “most” patients after THA is not supported. From an original sample of 640 patients, only 59 underwent THA without postdischarge PT-guided intervention. Of those 59, only 44 and 52 respectively were included in the 1-month and 6- to 12-month analyses. Thus, only about 8% of the original group reviewed for eligibility were actually assessed for outcomes without postdischarge PT. The study therefore does not show that >50% (“most”) THA patients meet criteria that justify eliminating formal postdischarge PT.

3. The authors provide insufficient data concerning the 520 subjects not randomized. Of these, 50 were excluded for not meeting inclusion criteria. An unreported number of those 50 were excluded because they were discharged “to an acute rehabilitation center, skilled nursing facility, convalescent home, or long-term care facility.” Thus, the authors excluded a number of patients who would in fact receive formal PT in a rehabilitation facility.

4. Details regarding the exact PT protocols received both in the hospital and postdischarge were not included. The absence of such detail impedes reproducibility of the study.

5. The primary and secondary outcome measures utilized were predominantly patient-reported outcomes. Overestimation of performance by patients has been reported after both knee (1) and hip (2) replacements. Further, Wright and colleagues concluded that both patient-reported and physical performance measures should be used when evaluating outcomes. (3)

6. The authors collected adherence data regarding patient daily exercise routines, yet they did not report the data. In a secondary qualitative summary, 20 participants (1/3 of the randomized sample in the formal PT group) crossed over to the unsupervised home-exercise group, citing burden of expenses and logistical constraints related to formal PT sessions. These perceived obstacles could have negatively impacted adherence to formal PT sessions in the remaining participants. Adherence data would have provided crucial information in addressing the primary research question of this study.

7. Although an intention-to-treat analysis was employed, a secondary sensitivity analysis excluding participants who crossed over may have helped to more robustly assess the comparative effectiveness of

these two treatment arms. The authors also could have shown the outcome trajectories of the crossover subgroups in Figures 2 through 4.

8. The authors cite the noninclusion of the posterolateral approach and the mixing of two different surgical approaches as potential limitations to the applicability of their findings. We think these limitations are far more significant than the authors suggest. Chechik et al. found that the posterior hip approach was the most preferred approach by orthopaedic surgeons in North America (69%), (4) which casts doubt on the generalizability of these findings.

9. Lastly, the authors noted that patients with higher socioeconomic and educational levels may have been more likely to participate in this study. Since socioeconomic data, education levels, and racial and ethnic characteristics were not reported, the generalizability of the authors' conclusions to the entire US population is questionable.

We believe it is of utmost importance to accurately characterize scientific findings. All studies have limitations and, as scientists, we acknowledge them and attempt to reconcile them with our scientific conclusions. Taking the results of this study and stating that formal physical therapy after THA is “not required” in the manuscript title is careless.

We hope this letter sparks collegial discussion. We encourage future research that sheds light on optimal and cost-effective post-THA rehabilitation.

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Conflict of Interest: None Declared

Article Author Response

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Article Author(s) to Letter Writer(s)

We appreciate the constructive comments by Dr. Hensley et al. and the opportunity to provide a response.

In this era of evidenced-based, cost-effective healthcare, decision-making has shifted to providing high quality care in a fiscally responsible manner. Some of the most common practices in medicine have come to enjoy widespread implementation based solely on historical norms. It is difficult to consider altering practices that have seemingly produced positive outcomes. Several years ago, we identified formal outpatient physical therapy (OPT) following total hip arthroplasty (THA) as one such practice that is costly and has little evidence to support or refute its routine use in all patients.

Since we reported the results of our randomized controlled trial (RCT), formal OPT has no longer been routinely implemented for a large majority of the nearly 5000 patients who undergo primary THA annually at our institution, with qualitatively the same excellent outcomes that we have come to expect from primary THA. However, it is important to note that about 15% of THA patients in our practice continue to utilize either in-home or outpatient professional physical therapy services. It is important that we protect these benefits for those who may need them the most. As such, we agree with our counterparts that precisely depicting the generalizability of a prospective, randomized study's findings is paramount, especially given the increasing impact of RCTs on payment models. However, we stand by our chief claim that our study methods and subsequent results provide strong evidence that formal OPT may not be required for up to 85% of patients after primary THA.

We address the comments made by Dr. Hensley et al. point by point below:

1) It is, in fact, true that all patients received formal OPT intervention prior to hospital discharge, and this is clearly delineated in our methods. However, greater than 90% of patients were discharged on

postoperative day 1 or earlier. Therefore, formal OPT services simply involved early mobilization and assessment of competence with essential home functions, such as ambulation, transfers, and stair climbing. This is clearly not the same as the extensive outpatient PT program that was our control intervention.

2) Hensley et al. make the argument that, because less than 10% of patients originally assessed for study eligibility were included in the investigational group forgoing formal OPT, our results cannot represent a majority of patients. However, this fraction is simply a standard function of how a randomized controlled trial is performed. While 640 patients were assessed for eligibility, 20% of eligible patients were actually enrolled in the study, a fairly typical yield for a study that required patients to submit to randomization and follow a strict protocol for a full 10-week period. The final number of patients enrolled in each study group (n=60) was determined statistically based on our sample size calculation. This is standard practice when performing an RCT, and has no impact in determining the generalizability of study results. Patients declining participation were not randomized, and were free to select a rehab strategy based on the recommendations of their operating surgeon.

3) In total, 50 patients (8%) did not meet study inclusion criteria. The largest group were patients discharged to a rehabilitation center, skilled nursing facility, or other extended care facility. However, about 11% of patients at our institution are discharged to such facilities, as it is our priority to safely transition the majority of patients to home. Many of our patients who require extended care have significant preoperative comorbidity or suffered perioperative complications. Further, patients with inflammatory or septic arthritis and revision or conversion arthroplasty were also excluded. We completely agree that our study results cannot be generalized to the relatively small group of patients that did not meet the inclusion criteria.

4) Patients receiving formal OPT were allowed to seek professional services at any facility employing licensed physical therapists. Importantly, this allowed for the most realistic clinical scenario, as it accounted for typical variation among practitioners. However, most patients participated in a traditional graduated regimen of exercises and stretching to improve strength, balance, and range of motion.

5) Patient-reported outcomes have unique value, because only patients can determine whether a procedure has successfully met their expectations and improved their quality of life. Ultimately, this is our primary goal in performing such an operation. However, we completely agree that objective measures of function would have been a powerful addition to this study, and we hope to see such physical measures

incorporated into future studies.

6) Hensley et al. bring up an important point that the burden of expenses and logistics most likely impacted adherence to formal OPT sessions. Likewise, it was unlikely that compliance with the home exercise program was perfect. However, we elected to impose an “intent-to-treat” study design and ignore patient adherence within our analysis. It was our goal to provide a study that would most closely mimic “real life” clinical practice, which is critical for the results of a study to have external validity outside of a research setting.

7) Unfortunately, a “per protocol” analysis would have been subject to significant systematic bias, in that older and lower-functioning patients were more likely to cross over into the formal OPT group. The “crossover” groups were also too small for any meaningful analysis of outcome trajectories.

8) While the posterolateral approach was not represented in this study, the direct anterior and direct lateral approaches are both widely utilized around the world. In fact, a growing interest in the DA approach continues to outpace other exposures. Although several studies have attempted to show an early functional benefit with the DA approach, there is no clear evidence that surgical approach has any meaningful impact on functional outcomes after THA.⁽¹⁻³⁾ Thus, it is our strong belief that the results of this study will be reproducible for surgeons employing a posterior exposure.

9) As always, it is possible that a selection bias could limit the external validity of our findings. However, we have found the home exercise program to be easily implemented within our larger practice.

Despite the best of efforts, even well-designed RCTs have clear limitations, and major clinical decisions should ultimately be made based on multiple, well-designed studies with reproducible results. It was not our intention to suggest that there is no role for formal OPT services after THA. There is a cohort for whom formal therapy is necessary, and we strongly agree that preserving these benefits is essential. The surgeon and patient should be allowed to determine this based upon a shared-decision making process. This was a major point of emphasis within our discussion, and prominently highlighted in the final statement within our conclusion. However, it is abundantly clear that formal OPT is not a required service following routine THA in all patients. We look forward to the contributions of other centers to better delineate the evidence on this topic.

References

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