A new responder criterion (relative effect per patient (REPP) > 0.2) externally validated in a large total hip replacement multicenter cohort (EUROHIP)

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Introduction

Total hip replacement (THR) is one of the most successful treatment procedures for patients with hip osteoarthritis; THR alleviates the symptoms (e.g., pain and stiffness) and degree of disability4–5. The success of THR can be measured as responder rate defined by Outcome Measures in Rheumatoid Arthritis Clinical Trials/Osteoarthritis Research Society International (OMERACT-OARSI) with patient reported outcome measurement tools (PROM’s)5,6. The responder rate for a surgical treatment (e.g., THR) contains valuable information and is easy to understand either for patients and general practitioners, surgeons and medical care providers12–14. For example in the multicenter EUROHIP study the responder rate for THR was 85.4%, meaning that 6 out of 7 patients had a clinical improvement above the level of a minimally clinically important difference and one of 7 patients does not profit from THR (being a “non-responder”)12. This information may be helpful either for decision making for the patients and for process amelioration for surgeons analyzing possible factors to become a responder or possible factors to become a “non-responder”.

But the method to calculate the responder rate is complex because one main criterion or two out of three subcriteria regarding pain or function needed to be fulfilled12. An easier method simple to calculate would be helpful to overcome this limitation. In the validation study of the relative effect per patient (REPP) [Fig. 1]
REPP = \frac{(\text{pre-treatment score}) - (\text{post-treatment score})}{\text{(pre-treatment score)}}

Example 1: pre-treatment score 48, post-treatment score 2; REPP = 48/2 = 24 = \text{non-responder}

Example 2: pre-treatment score 25, post-treatment score 16; REPP = 9/25 = 0.36 = \text{responder}

Example 3: pre-treatment score 13, post-treatment score 35; REPP = 22/35 = -0.63 = \text{non-responder}

Fig. 1. REPP formula and calculating REPP scores: three examples.

Statistical analysis

Descriptive statistics were used to determine the score variability before and after THR, as well as the number of responders. Cross tabulation of both methods was conducted to assess the percentage of patients who were appropriately classified. Receiver operator characteristic (ROC) curve analysis was used to assess the sensitivity, specificity, and percentage of patients who were appropriately classified compared to the newly proposed method, using the OARSI as the gold standard. Stata 13.1 software (Stata Corp., College Station, TX, USA) was used for all statistical analyses.

Results

All patients with complete outcome data from the preoperative and 12-month postoperative assessments (n = 845, comprising 63.7% of all included patients) were included. The average patient age was 65.7 years (range, 26–92 years).

The median WOMAC score of the patients before and after THR decreased from 58.3 to 15.6 (P < 0.001). The REPP-scores ranged from 1 to –1.5, peaking at approximately 1 and slowly decreasing to zero; there were few results near or below zero, as well as an outlier. For the EUROHIP cohort, the relative proportions of responders were 85.4% and 14.6% non-responders (12.7% unchanged, and 1.9% worse). Using the OARSI-OMERACT criteria, we identified 85.7% of the patients as responders.

Both methods classified nearly the same patients as responders with 98.8% sensitivity, 94.2% specificity and 98.1% correctly classified, demonstrating good validation of the new REPP method to calculate the responders [Fig. 2].

Discussion

Main findings

The criterion REPP > 0.2 to define a responder correlates with high sensitivity and also high specificity with the existing set of OARSI-OMERACT criteria. The responder rate can be calculated simple and easier with REPP method.
Strengths/limitations

The strength of this study is the large number of participating patients in 12 nations with PROM’s in 10 different languages at 20 centers allowing a reliable external validation of this new method.

Study limitations were the selection bias of patients and treatment.

The included patients (unilateral osteoarthritis of the hip, undergoing THR) were similar to those in the validation study.

A basic bias of the EUROHIP study group was that all participating surgeons and centers had a special interest in THR and in clinical science; therefore, the analyzed cohort may represent a positive patient selection and the responder rate may be higher than in general practice.

Author contributions

All authors have contributed to each of the three activities:

1) The concept of the REPP and the application of the new responder criterion the EUROHIP study cohort and the data acquisition of the cohort especially for the clinical part measuring the outcome
2) Drafting the article or revising it critically for important intellectual content
3) Approval of the final version, and will take public responsibility for the content of the paper.

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Competing interests

None.

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