

Author

Maciejasz, Pawel (Duderstadt DE) | Ph.D.

Otto Bock Healthcare GmbH - Clinical Research & Services

Title

Implementation of outcome measurement in daily routine of prosthetic clinics - challenges, choice of clinical instruments and collected evidence

Coauthors

Schlausch A, Grotrian JN, Rauch C, Hahn A

Summary

There is constantly increasing interest of various stakeholders to evaluate the outcomes of the prosthetic fitting in an objective way. In this paper we describe the experience with the international prosthetic outcome registry (6 prosthetic clinics, 3 countries) and present the preliminary results.

Introduction

As health care systems in many countries move toward pay for performance systems, amputation research is transitioning to examining patient-oriented outcomes [1]. Prosthetic clinics and manufactures of prosthetic components are asked to provide high quality evidence that a specific prosthetic fitting is beneficial for patients. However, high quality clinical studies in the field of prosthetics are rare. Due to the fact that each prosthetic fitting is very individual and influenced by many factors finding an appropriate study sample is challenging and costs of such studies are not negligible.

A high-cost clinical study is not the only way to prove patient benefit of medical treatment. In this paper we show that clinical registry, in which prosthetic fittings performed in prosthetic clinics are documented in a systematic way, may also be a source of high-quality evidence of patient benefit.

Methods

An outcome registry of prosthetic fittings has been developed and implemented in 6 prosthetic clinics in 3 countries (Germany, Ireland and India). After receiving a training in performing outcome measures the participating clinics document in the registry in a systematic way prosthetic fittings of lower limb amputees. Each fitting is documented with clinical outcome

measures before the fitting, after the fitting and during the follow-up visits. The outcome measures include validated and standardized self-reported questionnaires, such as EQ-5D-5L, PLUS-M, LCI, ABC Scale, Socket Comfort Score, and the following performance-based tests: 6 Minute Walk Test, Timed-Up and Go and Four-Square-Step-Test. Implementation of outcome registry requires certain effort. In addition to regulatory requirements, also an adaptation of the data collection process to the local procedures in each clinic is needed. Also the support of the clinical staff within the participating workshops is essential.

Results

The project has started two years ago and we plan to include further clinics in the project in the near future. So far data were retrieved from 286 subjects, 79% male, average age 44.6 +/- 18.6. Amputation levels were transtibial (145), transfemoral (124), knee disarticulated (16). 34 subjects had double amputations. Mobility ratings (MOBIS grading) were MG1: 3%, MG2: 23%, MG3: 66% and MG4: 8%.

Such amount of data allows already now to show the impact of various prosthetic fittings on different aspects such as quality of live, balance confidence, comfort and mobility.

The comparison of pre- and post-fitting data shows an average improvement of: 11.9% in quality of live (QALY), 9.1% in locomotor capabilities (LCI) and 9.4% in balance confidence (ABC). In addition, the data indicate that prosthetic intervention not only increases mobility, but also improve all the other dimensions of quality of live measured with the EQ-5D-5L instrument (self-care, usual activities, pain/discomfort and anxiety/depression). A further stratification of data (e.g. depending on mobility level, age, amputation level, etiology) provides a more detailed analysis.

Conclusion

Collecting outcome measurement data in a systematic way in prosthetic clinics is feasible, albeit, challenging task. To establish a registry the support of the clinical staff within the participating workshops is essential. This effort is however well invested, when weighted against potential benefits. In short term, it is an objective prove of patient benefit from the fitting that may be used in discussions with patients and payers. In long term, it should help to identify the optimal prosthetic fitting for individual patients.

References

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