Inclusion criteria

- RCT
- Medical device of high-risk class IIb/III

Justification

According to MPG

Studies that are non-randomized, according to § 137h SGB V to be included in the German system of Diagnosis Related Groups (G-DRG). Since 2016, new medical devices of risk classes IIb/III have to undergo benefit assessment according to § 137h SGB V (Bundesministerium für Gesundheit, 2016).

Thus, the objective of our research was to investigate whether evidence criteria of drug benefit assessment are also applicable to medical devices of risk classes IIb/III and, if this is the case, to which extend.

RESULTS

We identified 2,320 hits, with 1,917 publications (CCTR93: 794, ME60: 1,123) published in 2015 and 403 publications (CCTR93: 69, ME60: 334) published in 2016, respectively (Figure 1). After elimination of duplicates, titles and abstracts of the remaining publications were screened by using defined inclusion criteria (Table 1) and were additionally selected for high-risk classes.

Finally, hits were categorized by study size, study duration, and blinding.

Table 1: Inclusion criteria for the evaluation of studies

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We identified 2,320 hits, with 1,917 publications (CCTR93: 794, ME60: 1,123) published in 2015 and 403 publications (CCTR93: 69, ME60: 334) published in 2016, respectively (Figure 1).

After screening of titles and abstracts, 1,745 publications could be excluded. Of the remaining 575 hits, more than 50% were excluded because the criterion of high-risk class was not met.

Thus, in total we identified 216 hits describing RCTs of medical devices of high-risk class IIb/III, presenting data on: (a) catheters (71 hits); and (b) prostheses (145 hits).

(a) Catheters

- Only catheters which remain in the body for > 30 days and which refer to high-risk classes were considered for further analysis.

(b) Prostheses

- Prostheses were differentiated into endoprostheses (which are out-of-body) and implants (endoprostheses, which are tissue-enclosed implants).

- After selection of the remaining publications of medical devices of high-risk class IIb/III, no publication addressing endoprostheses were found.

- However, 145 publications presenting data of implants were indicated and divided into passive/mechanical devices (136 hits) and active implants (9 hits). Passive/mechanical devices included stems, dental implants, artificial hip or knee joints as well as implants for stabilizing bone fractures. Active implants, in turn, were cochlear implants or cardiac pacemakers. No implants with long-term pharmacological depots were detected (Figure 2).

DISCUSSION & CONCLUSION

- Although publications were indexed as RCTs in the literature databases, 28% (483 hits) of the excluded hits/ publications were neither randomized nor controlled.

- Compared to RCTs in drugs, study size was relatively small (< 100 patients) and methodological aspects differed substantially from IQWIG-accepted approaches.

- Strictly applying criteria of benefit assessment of drugs, e.g., study duration, randomization and blinding, to the benefit assessment of medical devices does not seem to be feasible. Medical devices of high-risk class IIb/III would most likely be rejected in a benefit assessment. The diffusion of innovative medical devices into the health system is therefore likely to be hindered. In consequence, from the individual perspective, a loss of an added medical benefit and, from the social perspective, a loss of welfare cannot be excluded.

- Specific characteristics of medical devices might at least partly explain the differences in the methodological quality of studies of medical devices compared to studies of drugs.

- Therefore, from an individual as well as from the health-policy perspective, and in order to capture the added medical benefit to innovative medical devices in a comprehensive way, methodological adaptations are advisable.

REFERENCES


ACKNOWLEDGMENT

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METHODS

We performed a systematic literature research in Medline (ME60) and Cochrane Central Register of Controlled Trials (CCTR93) databases to identify randomized, controlled trials (RCTs) published between January 2015 and May 2016, using relevant MeSH and controlled terms as well as a validated filter for RCTs (Wong et al., 2006).

Since a comprehensive and unrestricted search for medical devices of risk classes IIb/III is neither practical nor feasible, we limited our search to representatives of these risk classes. Therefore, catheters, prostheses and implants as well as surgical equipment, considering specific procedures, were chosen.

After elimination of duplicates, titles and abstracts of the remaining publications were screened by using defined inclusion criteria (Table 1) and were additionally selected for high-risk classes.

Finally, hits were categorized by study size, study duration, and blinding.

Figure 1. Flowchart of bibliographic literature research - search for RCTs with medical devices to be evaluated

Figure 2. Study characteristics of identified medical devices of high-risk class IIb/III

OBJECTIVE

- Medical devices are characterized as products of medical purpose, assigned for application in humans and which do not have a main pharmacological, immunological or metabolic effect (Bundesministerium für Gesundheit, 2016).

- Since 2016, new medical devices of risk classes IIb/III have to undergo benefit assessment according to § 137h SGB V to be included in the German system of Diagnosis Related Groups (G-DRG).

- Thus, the objective of our research was to investigate whether evidence criteria of drug benefit assessment are also applicable to medical devices of risk classes IIb/III and, if this is the case, to which extend.