Abstract: P6138

Quality of clinical trial evidence on devices and drugs approved to treat coronary artery disease

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Topic(s):
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Citation:
Background: Regulatory approval of drugs and devices follow two different pathways. Whether different approval pathways underlie meaningful differences in quality of clinical trial evidence is unknown. We aimed to compare the quality of evidence of clinical trials that served as a basis for approval by the U.S. Food and Drug Administration (FDA) of drugs and devices used for the treatment of coronary artery disease.

Methods: FDA databases were searched for devices (i.e., coronary artery drug-eluting stents) and drugs (i.e., agents targeting atherothrombosis) approved between January 1st, 2001 and December 31st, 2017. FDA medical reviews were screened to identify trials that served for approval purposes. The pre-specified primary outcome was the prevalence of randomized trials used for approval (i.e. number of randomized trials/overall number of trials).

Results: A total of 97 trials were identified, 39 serving for approval of 13 devices and 58 serving for approval of 8 drugs. Devices were evaluated by fewer trials per item as compared with drugs (3.0±1.4 vs. 7.3±5.3, P=0.012) with similar study size (501 [100-1314] vs. 379 [183-904] patients per trial, P=0.55). Trials evaluating devices were less frequently randomized (56.4% vs. 94.8%, P<0.001) and more frequently designed powered for clinical endpoints (53.8% vs. 17.2%, P<0.001) as compared to those evaluating drugs. Use of randomization declined over time among trials supporting FDA approval of devices. In addition, significant differences were present between trials evaluating devices and those evaluating drugs in terms of study design, comparator used, blinding to treatment allocation, primary hypothesis, primary endpoint, and type of patients included.

Conclusions: There are substantial differences in clinical trial evidence serving for FDA approval of devices and drugs used for treatment of coronary artery disease. The lower degree of randomized evidence used for approval of devices as compared to drugs raises some concerns, particularly in view of its decline over time.
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