A Meta-analysis for Major Complications Between Traditional Pacemaker and Leadless Pacemaker

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Abstract

Objectives To compare the major complications between leadless pacemaker (LP) and traditional pacemakers(TP).Background The TP shows some advantages in avoiding pocket- and lead-related complications over the TP and is increasingly used in clinical practice. However, the clinical effect of LP remains controversial.Methods PUBMED、EMBASE、The COCHRANE LIBRARY、CNKI and WANGFANG databases were searched from July 2013 to August 2018. Data concerning the study's design, patients' characteristics and outcomes were extracted. The primary end-point is the major complications. The second end-points are elevated pacing threshold, cardiac perforation/effusion, device dislodgement and vascular events.Results A total of 6 studies fulfilled the inclusion criteria. Only 4 of which can provide the data of major complications. The main complications of LP were statistically significantly decreased compared with that of TP(OR 0.41,95%CI:0.29-0.56,P<0.00001,I2=42%).We extracted the data of elevated pacing threshold, cardiac perforation/effusion, device dislodgement and vascular events in 4 other of these 6 studies. There was no significant difference in elevated pacing threshold (OR 0.95, 95%CI:0.24-3.70,P=0.94, I2=31%), cardiac perforation/effusion(OR 1.78,95%CI:0.33-9.58, P=0.50,I2=87%), vascular events (OR1.58, 95%CI:0.45-5.53, P=0.47,I2=47%) and device dislodgement(OR 0.22,95%CI:0.01-5.69,P=0.36,I2=81%) between LP and TP.Conclusion Compared with TP, LP showed a significantly decreased risk in major complications. This indicates that LP has a good prospect to be applicated in clinical practice.

Background

Since the first cardiac pacemaker was implanted in the human body in 1958, the pacemaker technology has been continuously improved to be a mainstay for the treatment of many major clinical problems, such as sick sinus syndrome, a high degree atrium-ventricle conduction block, etc. However, the pocket- and lead-related complications brought by traditional pacemaker (TP), such as infection and hematoma, have gradually are getting more attention[1].

In order to reduce the occurrence of these complications, the concept of leadless pacemakers (LP) was proposed in the 1970s[2]. With continuous research and development, LP currently in use include two types.1Nanostim™ Leadless Pacemaker System (LCP)[3];2Micra™ Transcatheter Pacing System (TPS)[4]. LP has a smaller volume than TP and is easier to implant[3,4]. With the increasing use of the LP, Mengi S et al.[5] reported that LP has a low risk of major complication, but Cantillon et al.[6] found an alarmingly high incidence of cardiac perforation/effusion and vascular events in short-term follow-up among patients implanted LP.

It is controversial that which one of the two pacemaker systems is better. Therefore, this meta-analysis was conducted to answer this issue.

Methods

2.1. Search strategy

A systematic search in PubMed, EMbase, The Cochrane Library, CNKI and WangFang databases which were publicated from July 2013 to August 2018 was performed. Studies eligible for inclusion were identified by using the following search strategy:1st run: “leadless pacemaker ”OR “leadless cardiac pacemaker ”OR “ Micra transcatheter pacing ”OR “leadless pacing ”OR “leadless cardiac pacing”，2st: “traditional pacemaker” OR “conventional pacemaker” OR “permanent pacemaker” OR “standard pacemaker”,3st: “effect” OR “therapeutic effect” OR “Treatment outcome” OR “Treatment effect” OR “therapeutic efficacy” OR “efficacy” OR “complication”,4st: 1st AND 2st AND 3st.

2.2. Selection criteria

The methodology involved in this meta-analysis is recommended in accordance with the guidelines of QUO-RUM (Quality of Reporting of Meta-analyses) and Cochrane Collaboration[7,8].

2.2.1. Inclusive criteria or exclusive criteria

Inclusive criteria: 1. The studies must include a comparison of LP and TP; 2. Detailed data can be extracted to compare the parameters of primary and second endpoint; 3. Language restriction: English and Chinese only included.

Exclusive criteria：1. Duplicate literature；2. single-arm study；3. Raw research data cannot be obtained or studied；4. Review, case report or animal experiments, etc.; 5. Other languages except English and Chinese.

2.2.2. Endpoints

Primary end-point: major complications, which were defined as system- and procedure-related events resulting in death, permanent loss of device function, hospitalization, prolonged hospitalization by 48 hours, or system revision[9].

Second end-points: elevated pacing threshold, cardiac perforation/effusion, device dislodgement and vascular events (embolism and thrombosis).

2.3. Literature screening, data extraction and quality evaluation

Di-yu Cui and Xiao-rui Chen independently screened the literature, and extracted the data, and evaluated the methodological quality of the included studies according to inclusive and exclusive criteria. In case of disagreement, discuss the settlement or submit it to the third person for assistance (Yun-qing Chen). The self-made data extraction table was used to extract the data, and the extracted content mainly included: 1.the general characteristics and basic conditions of the research; 2.the quality of the reaction research; 3. the specific method of the intervention; 4. the clinical outcome index. Methodological quality of the included studies using the methodological index of non-randomized controlled studies

(MINORS)[10].According to this method, the studies were divided into three levels of low, medium and high quality according to their MINORS scores of ≤8, 9-16 and≥17 points respectively.

2.4. Statistical analysis

Data processing was performed with Rev Man 5.3 software from the Cochrane Collaboration. The count data was analyzed by the odds ratio (OR) and its 95% confidence interval (CI) as the effect size. Heterogeneity test was carried out by χ2 test. When $P \geq 0.10$, $I^2 \leq 50\%$, the random effect model was used for meta-analysis; when $P < 0.10$, $I^2 > 50\%$, the cause of heterogeneity was first searched, which may lead to Sub-group analysis of heterogeneity factors. If there is statistical heterogeneity between the study's results and no clinical heterogeneity or difference do not reach statistical significance, a random effects model meta-analysis is used, and the results are interpreted with caution. The analysis was described if the data cannot be merged.

Results

3.1. References screening

In our database research, 120 references were retrieved: 28 references were from PubMed, 41 articles were from Embase, 2 references were from CNKI, 2 papers were from Cochrane Library, 31 references were from WangFang Database and 16 articles were from other ways (references). 30 references were excluded because of reduplicated references by Endnote software. 50 irrelevant references were excluded after reading titles and abstracts. Therefore, 40 references were left for further review. After reading the full text, 34 references were excluded: 15 references because of single-arm clinical trials,12 references reported as review, and 7 articles conducted in animal experiments. Finally, 6 studies (Cantillon et al.,2018[6]; Fleur VY Tjong et al.,2018[11]; Duray et al.,2017[12]; A. Carabelli et al.,2018[13]; Piccini et al.,2017[14]; Mikhael F et al.,2018[15]) were included in the systematic review **(Fig.1, Table1)**.

3.2. Characteristic of included papers

Of all the included studies, none of them was a randomized controlled clinical trial. In five of these studies, all data of LP were from the current ongoing clinical trials, while data of TP were from previous clinical trials. One study's patients[11] with TPs were 1:1 propensity score matched to patients with LPs. One study's patients[6] with TPs were 2:1 propensity score matched to patients with LPs. The types of LP trial in these 5 studies were all prospective studies and the types of TP trials in these 5 studies were unclear. Only one study was designed as head to head comparative trial between TP and LP, which was a single center study. More details were shown in **Table1**.

3.3. Data extraction

3.3.1. Primary end-point (major complication):

5 of 6 studies fulfilled the primary end-point. Piccini et al.[14] study didn't provide the data of primary end-point. However, after reading the full text, the data of LP in Cantillon et al.[6]was derived from the multi-central clinical trial LEADLESS II, the data of TP was derived from the data published by Truven Health 6. The LP data from Duray et al.[12]was derived from a perspective, one-arm study: The Micra Transcatheter Pacing Study, data of TP from the previous six Medtronic trials. Patients with LP in Mikhael F et al.[15] study was derived from the clinical trial: The Micra TPS Post-Approval Registry, and the data of TP were the same with the data from Duray et al. [12]. Carabelli et al.[13]was a comparative study of complications involving both two pacemakers. In Fleur VY Tjong et al.[11], patients with LP have participated in at least one or more of the following clinical trials: 1) LEADLESS Trial (NCT01700244), 2) The Leadless Observational Study (NCT02051972), 3) The Leadless IDE Trial (NCT02030418), 4) The Micra TPS Study (NCT0200487), 5) The Micra TPS Post-Approval Registry (NCT0253618). The data of traditional single-chamber pacemakers come from the FOLLOWPACE forward-looking global in 23 centers in the Netherlands array research.

According to the above description, the study of Fleur VY Tjong et al. was excluded because the data of the LP was included into one or more following included studies: Cantillon et al., Duray et al. and Mikhael F et al. Finally, 4 studies were reserved to perform a meta-analysis about the major complications of LP and TP. 2667 TP patients of Mikhael F et al. were the same people as that of Duray et al., who was originally from the Reynolds et al study. So, we extracted only once about the data of TP from Reynolds et al. study. Because the data of LP from the two studies (Mikhael F et al. and Duray et al.) were completely different, so we combined them as the total data of LP. This data was shown as a combination (Duray2017+ Mikhael F2018) in Figure1. Finally, based on the data of 4 studies (Cantillon et al.,2018; A. Carabelli et al.,2018; combination (Duray2017+ Mikhael F2018)), 3333 patients were included into LP group and 4175 patients were included into TP group.

3.3.1.1. Major complications of TP:

4 studies[6,12,13,15] enrolled 3333 patients altogether and the incidence of major complications of TP was 11.5%, 9.7% and 7.8%（combined）respectively. The average rate was 9.7%, mainly for lead- and pocket-related complications, some for infection, thoracic trauma and electrode dislodgement.

3.3.1.2. Major complications of LP:

4175 patients implanted with LP were enrolled in the 4studies [6,12,13,15] and the incidence of major complications was 5.8%, 6.9% and 2.8%（combined） respectively and the mean rate was 5.2%. The major complications included cardiac perforation/effusion, device dislodgement, elevated pacing threshold and vascular events.

3.3.1.3. Major complications with LP vs TP:

The incidence of major complications of LP and TP in the four trials is shown in Figure1. LP show an significant advantage on the main complications over TP (OR 0.41,95（CI:0.29-0.56,P<0.00001,I^2=42（),

and more detailed data can be seen in **Fig. 2**.

3.3.2. Second end-points:

4 of 6 studies fulfilled the second end-point. In the Piccini et al. study, the data of LP was from The Leadless IDE Trial and the data of TP was from the Capture study. The characteristics of the other three studies were described above. Fleur VY Tjong et al. and Piccini et al. studies were used to analysis the rate of elevated pacing threshold. Combination (Duray2017+ Mikhael F2018) and Cantillon et al. studies were used to analyze the rate of cardiac perforation/effusion. Cantillon et al. and Duray et al. studies were used to analyze the rate of device dislodgement and vascular events.

3.3.2.1. Detailed complications with LP vs TP:

There was no significant difference in elevated pacing threshold (OR 0.95, 95%CI:0.24-3.70,P=0.94, I^2=31%)(**Fig.3**) , cardiac perforation/effusion（OR 1.78,95%CI:0.33-9.58, P=0.50,I^2=87%)(**Fig.4**), vascular events (OR1.58, 95%CI:0.45-5.53, P=0.47,I^2=47%)(**Fig.5**) and device dislodgement(OR 0.22,95%CI:0.01-5.69, P=0.36,I^2=81%)(**Fig.6**) between LP and TP.

Discussion

4.1. Main findings

This meta-analysis showed LP was associated with lower incidence of major complications compared with TP. There is no significant difference between TP and LP in the incidence of elevated pacing threshold, vascular events, device dislodgement and cardiac perforation/effusion. To the best of our knowledge, it is the first meta-analysis that compare with the major complications between LP and TP. And the results indicate that LP is predominant in terms of security compared with TP. Therefore, LP has great prospect in clinical practice in the future.

From Fig. 2, we can see that the main complication rate of TP is higher than that of LP (OR 0.41,95CI:0.29-0.56, P<0.00001, I^2=42%). This mainly depends on the advantages of its design and implantation way. The LP has no lead and capture, and no longer interferes with the blood vessels after implantation, which is unlike to what is done with TP. Instead of being present under the skin, it is fixed in the myocardium after LP implantation.

In addition to the trials included in this research, more large-scale trials on LP have been conducted described as following. The overall major complication rate was 4% in the Micra TPS study, 1.5% in the Micra post-approval registry, 5.3% in the Leadless Observational Study (The most frequently occurring events were cardiac perforation (1.3%), device dislodgement (0.3%), and vascular complications (1.3%)), 6.7% in the LEADLESS II Clinical Trials and 6.5% in the LEADLESS study. The longest follow-up time in these studies was 12 months, and some of these studies are still ongoing, but it is worthy to be confirmed that LP is safety in terms of short-term complications.Among the complications of these trials, the common complications include cardiac perforation/effusion, device dislodgement and vascular events.

Although these three complications were also studied in our study, the results were not statistically significant (Fig.4-6).

In terms of the implantation process of LP whether it is Nanostim or Micra pacemaker system, the implantation procedure is similar, utilizing a percutaneous femoral, catheter-based approach to introduce and advance the leadless pacemaker to the right ventricle (RV). After reaching the RV, the two leadless pacemakers are fixed to the heart muscle in different devices. The Micra device has a tine-based fixation mechanism, and the Nanostim is fixated using a helical screw. For this fixation method, there is a certain degree of risk. If the fixed position is deep, it is easy to occur with heart perforation. While when the place is shallow, it tends to appear device displacement. In general, the depth of the implant site is inseparable with the proficiency of the operator. Currently there is a study demonstrated the importance of learning curves during the process of Nanostim LP implantation. Procedure efficiency improved through increased operator's experience, according to a decrease in the incidence of complications, procedure duration and repositioning attempts. In regard to Micra LCP, Lluis Mont et al. showed that the perforation and effusion rate with the Micra leadless pacemaker has declined to <1.0% from initial to post-approval experience and remains in-line with rates reported in the literature for transvenous systems.

As the result of the LP is implanted from femoral vein, it is essential to affect the blood vessels and may cause the occurrence of thromboembolism. Incidence in evaluating elevated pacing threshold, our study suggests the LP with TP no statistically significant difference (Fig3). Piccini et al. showed that most Micra patients with elevated pacing threshold decrease after implant. Patients with a pacing threshold of 2 V had a significant risk of persistently elevated pacing thresholds of 42 V at follow-up. The patients with 2V pacing threshold have such a stronger association with elevated thresholds in the future. It is currently only speculated that there is a poor contact or device fibrosis which may affect the incidence rate of elevated pacing threshold. However, it still needs a further investigation.

Limitations

There were no randomized controlled studies in the included studies, and the follow-up time of these studies was different. The follow-up time for these 6 studies was 1 months [6], 800 days [11], 12 months [12], 6 months [13,14] and 6.8 ± 6.9 months [15]. For the research method, in addition to the tests of Carabelli [13], which included both leadless pacemakers and traditional pacemaker implants, there is no head to head randomized comparison. In this study, we combined two data of LP from two researches, because they had the same group of historical control patients. Nevertheless, the combined two trials have difference in the baseline demographics, so the overall result can be affected. In terms of population, there is no data on the trial of LP in China. For the Asian population, 36 people in the Japanese population and 690 people in the rest population [24] have been followed up for 1 year, suggesting that there is no significant difference in the probability, and the rest of the results will be explored by more relevant clinical trials.

Conclusions

Our meta-analysis appears to favor that LP has a safer application compared with TP when related to major complications. This indicates that LP has potential more clinical applications in future.

Although only single-chamber LP has been put into clinical use, dual-chamber pacing is already under investigation [25]. However, the application of LP is still controversial, and more randomized controlled studies are needed to explore the safety and practicality of it.

Abbreviations

leadless pacemaker (LP) traditional pacemakers（TP）

Declarations

8. **Author's contributions**

C.S.Y. and C.X.R. designed research, performed research, analyzed data, and wrote the paper. In case of disagreement, discuss the settlement or submit it to the third person for assistance (Yunqing Chen).

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10. **Consent to publish**

Not Applicable

11.Funding

No funding was obtained for this study.

12. **Competing interests**

All authors have no competing interests.

13.Availability of data and materials

We have indeed provided all raw data on which our study is based.

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Tables

Table1 Baseline characteristics of studies

study	year	study design		total		incidence		age(years)		selx(male)		follow-up		quality
		LP	TP	LP	TP	LP	TP	LP	TP	LP	TP	LP	TP	
Cantillon	2018	a prospective, nonran-domized, multicenter clinical study trial	n.a.	718	1436	42	165	75.6±11.9	76.1±12.3	62%	63%	1 month	n.a.	moderate
		TPs were 2:1 propensity score matched to LPs												
Carabelli	2018	a single center study		72	72	5	7	n.a.	n.a.	n.a.	n.a.	6 months	n.a.	moderate
Fleur VY Tjong	2018	prospective,participated in one or more trials[a]	n.a.	220	220	9	21	78	n.a.	61%	n.a.	800 days	n.a.	high
		TPs were 1:1 propensity score matched to LPs												
Duray	2017	prospective,non-randomized,worldwide trial	n.a.	726	2667	29	203	75.9±10.9	n.a.	58.80%	n.a.	12 months	12 months	moderate
		n.a.												
Piccini	2017	a prospective, multi-site, single-arm study	a contemporary study[b]	711	538	83	50	n.a.	n.a.	n.a.	n.a.	6 months	n.a.	moderate
		n.a.												
Mikhael F	2018	prospective,non-randomized,multi-center registry	n.a.	1817	2667	41	196	75.6±13.5	n.a.	61.10%	n.a.	6.8±6.9 months	n.a.	high
		n.a.												

a:1) LEADLESS Trial (NCT01700244), 2) The Leadless Observational Study (NCT02051972), 3) The Leadless IDE Trial (NCT02030418), 4) The Micra TPS Study (NCT0200487), 5) The Micra TPS Post-Approval Registry (NCT0253618);

b:The Capture Study

Figures

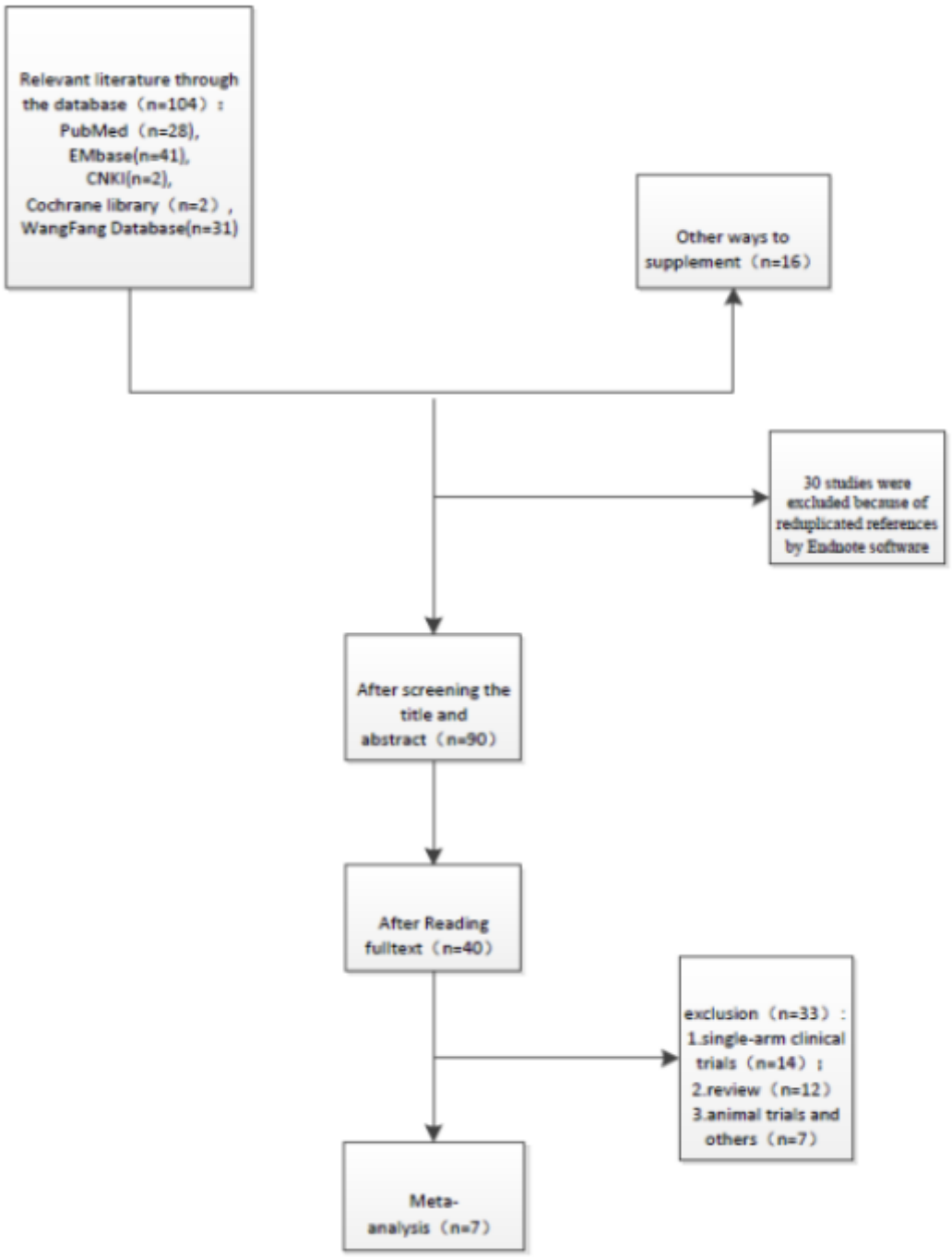

Figure 1

Selection of studies for inclusion in review/meta-analysis

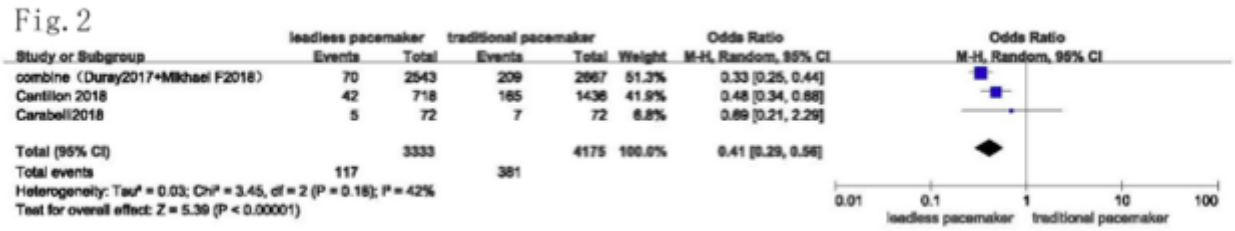

Figure 2

Forest plot of major complications

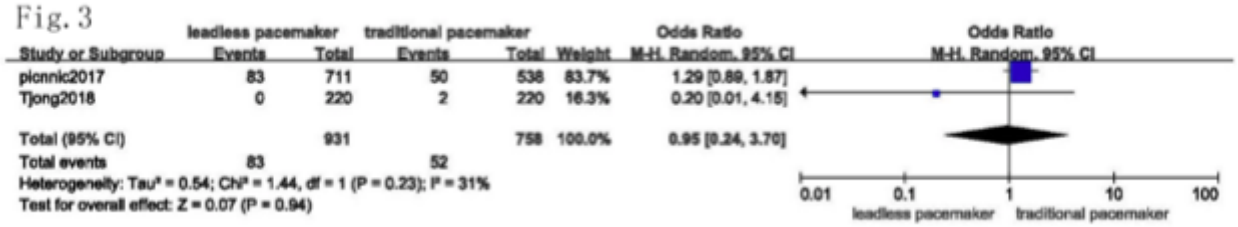

Figure 3

Forest plot of elevated pacing threshold

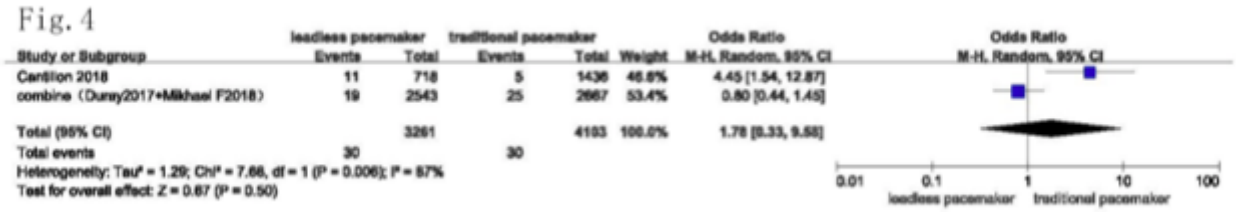

Figure 4

Forest plot of cardiac perforation/effusion

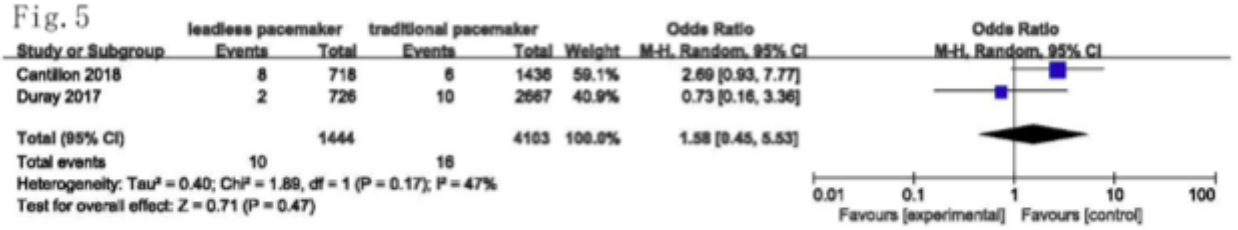

Figure 5

Forest plot of vascular events

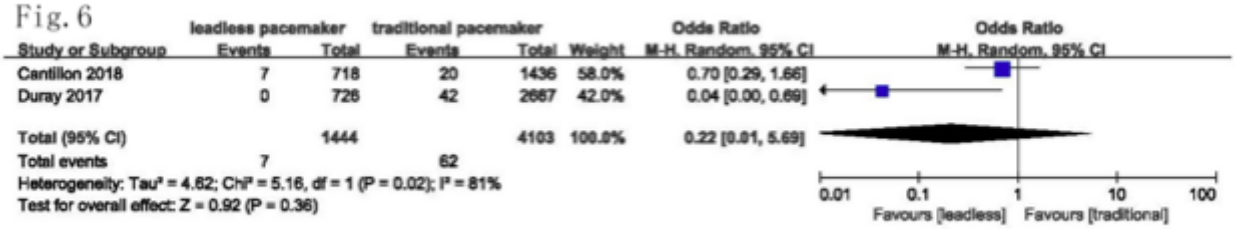

Figure 6

Forest plot of device dislodgement

Supplementary Files

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