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Pattern of relapse in patients with stage IB1 cervical cancer after radical hysterectomy as primary treatment. Minimally invasive surgery vs. open approach. Systematic review and meta-analysis.

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HIGHLIGHTS

- The MIS approach doesn't modify the relapse location in stage IB1 cervical cancer.
- The Open approach doesn't modify the relapse location in stage IB1 cervical cancer.
- More studies are needed to determine the factors that modify the site of relapse.

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ABSTRACT

Background. After the LACC trial, the SUCCOR study, and other studies, we know that patients who have undergone minimally invasive surgery for cervical cancer have worse outcomes, but today, we do not know if the surgical approach can be a reason to change the pattern of relapses on these patients. We evaluated the relapse pattern in patients with stage IB1 cervical cancer (FIGO, 2009) who underwent radical hysterectomy with different surgical approaches.

Methods. A systematic review of literature was performed in PubMed, Cochrane Library, Clinicaltrials.gov, and Web of science. Inclusion criteria were prospective or retrospective comparative studies of different surgical approaches that described patterns or locations of relapse in patients with stage IB1 cervical cancer. Heterogeneity was assessed by calculating I2.

Results. The research resulted in 782 eligible citations from January 2010 to October 2020. After filtering, nine articles that met all inclusion criteria were analyzed, comprising data from 1663 patients who underwent radical hysterectomy for IB1 cervical cancer, and the incidence of relapse was 10.6%. When we compared the pattern of relapse (local, distant, and both) of each group (open surgery and minimally invasive surgery), we did not see statistically significant differences, (OR 0.963; 95% CI, 0.602–1.541; $p = 0.898$), (OR 0.788; 95% CI, 0.467–1.330; $p = 0.542$), and (OR 0.683; 95% CI, 0.331–1.407; $p = 0.630$), respectively.

Conclusion. There are no differences in patterns of relapse across surgical approaches in patients with stage IB1 cervical cancer undergoing radical hysterectomy as primary treatment.

1. Introduction

From the results of the LACC trial in 2018 [1], the SUCCOR study in 2020 [2], and others [3], we know that patients who undergo radical hysterectomy for minimally invasive surgery (MIS) as primary treatment for early cervical cancer have worse outcomes in terms of

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disease-free and overall survival. Subsequently, the publication of some meta-analyses confirmed these results [4,5].

After these publications, we observed a growing interest in understanding why patients who underwent radical hysterectomy via MIS for early cervical cancer presented a higher risk of relapse and mortality than others. There is also a great interest and effort to find out what other variables besides the approach, such as the preoperative cone [6] and protective maneuvers during surgery [2], might affect the likelihood of relapse, using some of these variables to create a score to predict which patients have a higher risk [7].

Meanwhile, in the last decade and especially in recent years, some studies reported as part of their analysis the pattern of relapse between different surgical approaches without a clear difference, perhaps because the total number of relapses included in these studies was low or because some studies included different oncologic stages in their analyses [8–13].

For this reason, we decided to perform a systematic review and meta-analysis with the primary goal to evaluate the pattern of relapse among different surgical approaches in patients with stage IB1 cervical cancer who underwent radical hysterectomy as primary treatment.

2. Materials and methods

We performed this meta-analysis according to PRISMA and MOOSE guidelines [14]. We did not register protocol, and because of the nature and design of the study, Institutional Review Board approval was declined. All inclusion and exclusion criteria for the studies to be selected were defined, as well as the method for data extraction and quality assessment before starting the data search.

2.1. Data sources and searches

A single investigator searched four databases (PubMed, Web of Science, Cochrane Library, and Clinicaltraials.gov) for studies reporting the correlation between surgical approaches and relapse patterns in patients undergoing radical hysterectomy as primary treatment, published between January 2010 and November 2020. The language limit was set to English.

The terms used for the search included "pattern relapse cervical cancer," "pattern recurrence cervical cancer," "open vs laparoscopic cervical cancer relapse," "pattern recurrence cervical cancer approach," "laparoscopic pattern of relapse cervical cancer," and "laparoscopic pattern of recurrence cervical cancer." For example, in searching PubMed, we used the following Medical Subject Heading (MeSH) terms: open[All Fields] AND vs[All Fields] AND ("laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields]) AND ("uterine cervical neoplasms"[MeSH Terms] OR ("uterine"[All Fields] AND "cervical"[All Fields] AND "neoplasms"[All Fields]) OR "uterine cervical neoplasms"[All Fields] OR ("cervical"[All Fields] AND "cancer"[All Fields]) OR "cervical cancer"[All Fields]) AND ("recurrence"[MeSH Terms] OR "recurrence"[All Fields] OR "relapse"[All Fields]).

2.2. Study selection

A single investigator screened the titles and abstracts identified by the search to exclude duplicate and irrelevant articles (studies not dealing with the topic, reviews, and letters to the editor). Studies that only analyzed and reported the pattern of recurrence in a single surgical approach or compared only laparoscopic and robotic surgery were excluded. We included studies covering different surgical approaches (open vs. MIS or open vs. laparoscopic or open vs. robotic or open vs. laparoscopic vs. robotic), which also reported the pattern of relapse in different groups, from which we were able to obtain data for stage IB1 patients (tumors smaller than 4 cm.) according to the FIGO classification prior to 2018.

The full texts of the remaining articles were independently reviewed by one investigator to identify potentially eligible studies based on the following criteria: prospective or retrospective cohort observational studies comparing outcomes between different surgical approaches, usual histology subtype, and detailed description of relapse location in patients with stage IB1 FIGO staging. Exclusion criteria were the previously mentioned criteria, insufficient information about the location of relapse, and the impossibility to obtain the location of relapse in stage IB1 patients.

The reference list of the included studies was examined to identify any other relevant research. In case of missing data, we contacted the authors; if no response was obtained, the article was excluded.

2.3. Data extraction and quality assessment

One investigator independently extracted data from each included study. The following information was obtained: study design, mean age and range of patients, BMI, number of participating centers, number of surgeons, surgery performed, mean and range of surgery time, follow-up protocol, mean and range of follow-up time, total number of patients, total number of relapses, total number of open approaches, total number of relapses in open approaches, total number of MIS approaches, total number of relapses in MIS approaches, and FIGO staging classification.

One investigator, based on the different classifications used by the authors, classified relapse location as local, distant or both locations. Local relapse was defined as any relapses located in the pelvis, pelvic wall, vaginal vault, or pelvic lymph nodes. Distant relapse was defined as any relapses localized outside the pelvis and relapse in lymph nodes without reported localization; and both localizations were defined as the presence of relapse in the pelvis and in other locations concurrently.

One investigator assessed study quality using the risk-of-bias tool for observational studies using the Newcastle–Ottawa scale, which is based on three main domains: "selection," "comparability," and "outcome." The "selection" domain includes four items (representativeness of the exposed cohort, whether the unexposed cohort is from the same community as the exposed cohort, determination of exposure, and demonstration that the outcome of interest was not present at baseline; ratings can be up to six stars). The "comparability" domain includes one item (comparability as defined by control for confounding factors; ratings can be up to two stars). The "outcome" domain includes three items (outcome assessment, sufficient follow-up time, and adequacy of follow-up; ratings can be up to five stars). Study quality is scored as follows: good quality (3 or 4 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain), fair quality (2 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain), and poor quality (0 or 1 star in the selection domain OR 0 stars in the comparability domain OR 0 or 1 star in the outcome/exposure domain).

2.4. Statistical analysis

The magnitude of association used for all studies was odds ratio (OR) and its corresponding 95% confidence interval (95% CI). Between-study heterogeneity was assessed using Cochran's Q test and Higgins's I2 statistic. The combined overall estimate of the intervention effect was calculated using a random-effects model with the DerSimonian and Laird method. Forest plots were also used to evaluate the overall effect. Two-sided *P* values less than 0.05 were considered statistically significant. All statistical analyses were performed with Stata version 14 (StataCorp, 2015; Stata Statistical Software: Release 14; College Station, TX: StataCorp LP).

3. Results

A search in the electronic databases PubMed, Cochrane Library, Clinicaltrials.gov, and Web of Science was carried out with the terms "pattern relapse cervical cancer," "pattern recurrence cervical cancer," "open vs laparoscopic cervical cancer relapse," "pattern recurrence cervical cancer approach," "laparoscopic pattern of relapse cervical cancer," laparoscopic pattern of recurrence cervical cancer," "minimally invasive surgery versus abdominal surgery cervical cancer," and "minimally invasive surgery versus laparotomy cervical cancer." This resulted in 782 eligible citations from January 2010 to October 2020, of which 8 were duplicates and 715 were excluded based on the titles because they were not relevant to this meta-analysis or were reviews, case reports, book chapters, letters to the editor, phase 3 trials, and studies on other types of cancer such as otolaryngology cancer. Of the 61 remaining, 34 were excluded after reviewing their abstract because they did not compare postoperative results between approaches.

The full texts of the 25 remaining articles were read, one of which was not available in English and 15 did not provide the necessary information to elaborate on the table even after contacting the authors, so they were also excluded. Using the snowball method, we found two more articles prior to contact with the authors, and five articles were included directly after the research.

A total of nine studies [15–23] published between 2011 and 2020 were included in this meta-analysis. Fig. 1 shows a flowchart summarizing literature identification and selection.

A total of 1663 patients with stage IB1 uterine cervical cancer who underwent radical hysterectomy as first treatment were selected, and 180 cases of relapse were reported in the studies.

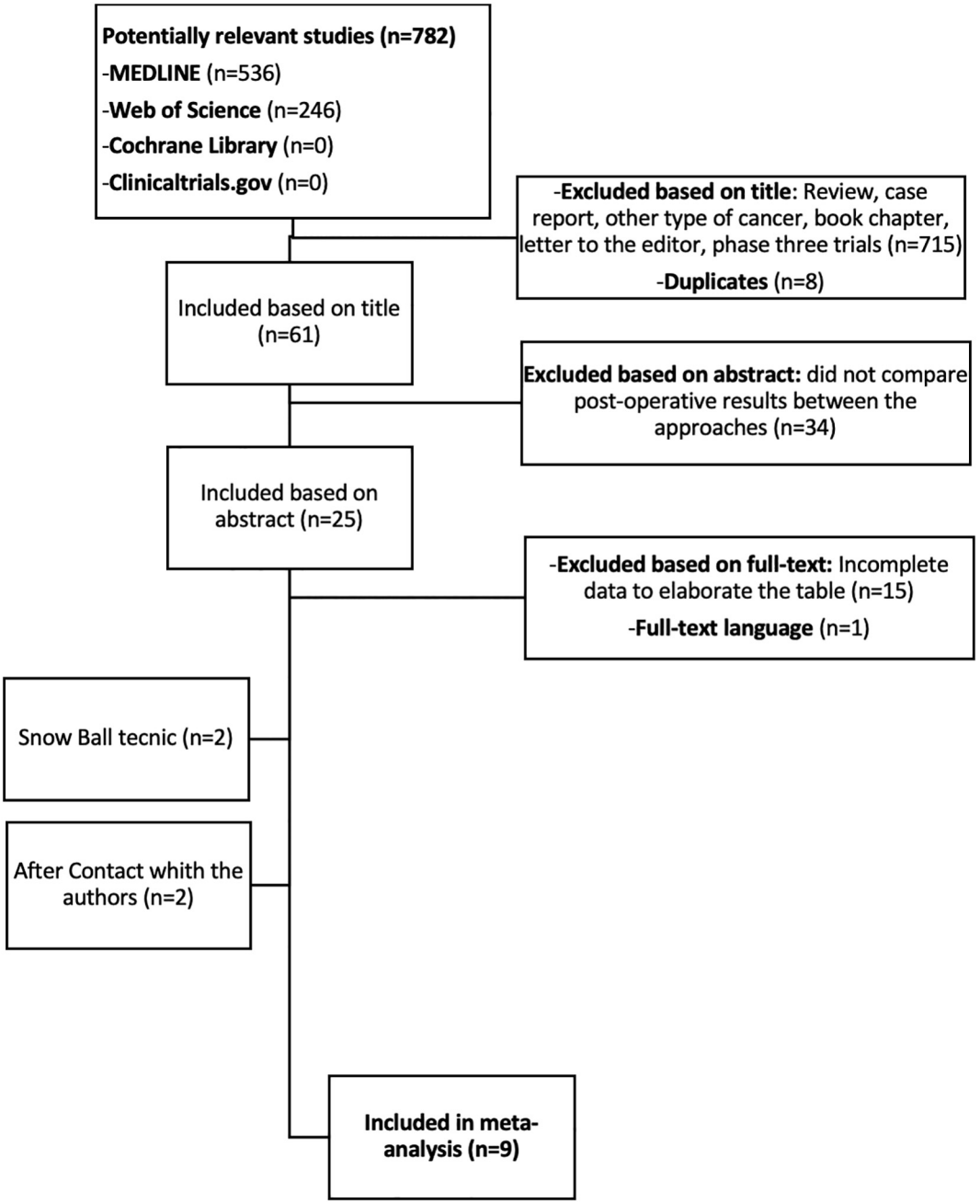

Fig. 1. Flowchart showing studies selection process.

Seven studies were retrospective and two were prospective, and all studies compared the outcome between the open approach and MIS. Two studies compared robotic versus open approach [17,18], but one of them did not perform robotic surgery in tumors larger than 3 cm [18]. One study compared the laparoscopic "no touch no look" approach versus the open approach [20], and another study analyzed only patients with tumors smaller than 2 cm. in diameter [19]. Only one study was multicenter [19], four mentioned the number of surgeons [15,16,18,22], and four reported surgical time with a rage of 110 to 419 min for open approach and 75 to 562 min for MIS [16,18,20,22]. Four studies mentioned protocol follow-up [15,16,21,23],. the most frequent follow-up protocol was a review every 3 months for 2 years, followed by every 6 months for 3 years and then annually for life. Meanwhile, one study did not report follow-up time [21], the lowest mean follow-up time was 25.4 months (0.2–95.1) [17] and the highest mean follow-up time was 112.2 months (52–162) [23]. Four studies did not mention the FIGO staging classification used [16,17,20,21], and one study did not report the surgery performed [22] (Table 1 and Supplementary 1).

Table 2 shows the quality assessment of the studies included in these reviews according to the Newcastle–Ottawa scale.

For the "selections" item, two of nine studies were considered a select group of the cohort under study because they examined tumors 3 cm. or less [18] and under 2 cm [19]. All studies determined exposure (in all cases, a histological diagnosis was provided). However, we consider that only in two studies [16,23] (those of prospective design), the outcome of interest was certainly unknown at baseline.

Regarding the item "comparability," we considered that the cohorts (women undergoing open and MIS HR) were comparable, as all studies in some way controlled for the main confounding factors (age of patients, type of surgery, histologic type, and histologic grade) except for one study [22] that did not report the type of hysterectomy performed. However, only one study [16] somehow compared all secondary confounding factors that were selected (description of inclusion or exclusion criteria, total number of surgeons, total number of centers, surgical time, follow-up protocol, and follow-up time).

Finally, regarding the "outcome" field, we considered that all included studies reported a complete follow-up (mean 24 months), only three of them had an adequate follow-up (one reported a follow-up of at least 36 months for all patients [21], and the other two reported a loss of less than 20% [19,23]), and seven studies reported on how to obtain the results [15–17,20–23].

All authors used a classification for relapses which allowed us to extract the information, using our definition for local, distant and both locations. When we analyzed the probability of local, distant, and both localization relapses between different surgical approaches, taking minimally invasive surgery as a referral group, we did not see statistically significant differences, (OR 0.963; 95% CI, 0.602–1.541; $p = 0.898$), (OR 0.788; 95% CI, 0.467–1.330; $p = 0.542$), and (OR 0.683; 95% CI, 0.331–1.407; $p = 0.630$), respectively (Fig. 2).

4. Discussion

In the present meta-analysis, we assessed the pattern of relapse of different surgical approaches in patients with stage IB1 cervical cancer treated with radical hysterectomy as primary treatment.

The main strength of our study is that, as far as we know, this is the first meta-analysis that addressed this issue. We have provided data that could be interesting in clinical practice, as we observed no difference in the pattern of relapse between different surgical approaches in a specific group of patients in an oncologic stage that currently could be one of the most studied subjects and a stage in which the surgical approach has more weight in the probability of recurrence [5,24]. We did not observe publication bias.

We decided to exclude patients with different oncological stages from IB1 because these studies could be considered to belong to a different clinical setting. We also decided to exclude studies that included only one surgical approach because in these studies, we cannot make a comparison of outcomes with those of other groups, and therefore, they do not represent the target population under study.

Nevertheless, we acknowledge that our study has some weaknesses. First, all data obtained might be biased, as some of the studies showed selection bias. Three of nine studies included a select group of patients, one of which included only patients with tumors less than 2 cm [19], . while another treated only tumors less than 3 cm [18]. Another study excluded patients treated with robotic surgery [15], and two of the studies performed patient matching [15,18]. As reported in some studies, tumors with smaller diameters have less risk of relapse [2,5], which could be a factor that decreases the probability of an event and, for that reason, could modify the results. Meanwhile, the small number of studies and events probably limited the power of this study and could be a reason for the nonsignificant differences.

Additionally, we only included nine studies; therefore, the power to detect covariates that explain the heterogeneity is low.

Notwithstanding, it should be noted that we are addressing the pattern of relapse in patients with cervical cancer. One question that may arise is whether this pattern offers any prognostic advantage for these women. From the data in the literature, we know that patients with nonpelvic relapse had significantly worse outcomes in overall survival [25,26].

We consider that the quality of the included studies was acceptable, but there is room for improvement in future studies, especially with regard to study design. As mentioned above, most of the studies showed selection bias, and most of them were retrospective.

Table 1
Main characteristics of the studies included in this meta-analysis.

Author	Year	Design	Type	N	Total Relapse	Open Approach	Open Relapse	MIS Approach	MIS Relapse	Surgery performed	Time F-U
Sert	2011	Prospective	Cohort	56	5	23	0	33	5	Piver Type III	Robot: **36** +/− 14.4 Lap: **56.4** +/− 14 Ope:**70**±21
Toptas	2014	Retrospective	Cohort	52	8	39	5	13	3	Type C1 Q-M	N/A
Kim	2019	Retrospective	Cohort	392	41	196	19	196	22	Type C Q-M	61.6
Kanao	2019	Retrospective	Cohort	163	13	83	8	80	5	Piver Type III	Ope: **31.3** (23.1–44.2) Lap: **30.2** (21.0–37.5)
Doo	2019	Retrospective	Cohort	105	20	56	8	49	12	Piver Type III	**25.4** (0.2–95.1)
Chen	2020	Retrospective	Cohort	325	16	196	5	129	11	Piver Type II-III	Ope: **49.5** (3–108) Lap: **51.8** (2–115)
Brant	2020	Retrospective	Cohort	178	20	75	8	103	12	N/A	Ope: **46.2** (0.4–131.4) Lap: **46.9** (0.2–146.7)
Zanagnolo	2015	Retrospective	Cohort	240	29	78	11	162	18	Type B < 2 cm or C1 > 2 cm Q-M	Ope: **50.38** (19.74–79.61) Lap: **35.84** (15.89–57.92)
Gil	2018	Prospective	Cohort	152	28	63	11	89	17	Type B < 2 cm or C1 > 2 cm Q-M	**112.4** (52–162)

Abbreviations: MIS, Minimal invasive surgery; F—U, Follow-up; Q-M, Querleu-Morrow; Ope, Open surgery; Lap: Laparoscopic Surgery; N/A, Not Available.

Table 2
Quality assessment of studies included according to the Newcastle-Otawa scale.

Author	Year	Selection	Comparability	Outcome
Sert	2009	★★★★	★★	★★
Toptas	2014	★★★	★	★★★
Zanagnolo	2015	★★	★	★
Gil- Moreno	2018	★★★★	★	★★★
Chen	2019	★★	★	★★
Doo	2019	★★★	★	★★
Kanao	2019	★★★	★	★★
Kim	2019	★★★	★	★★
Brant	2020	★★★	★	★★

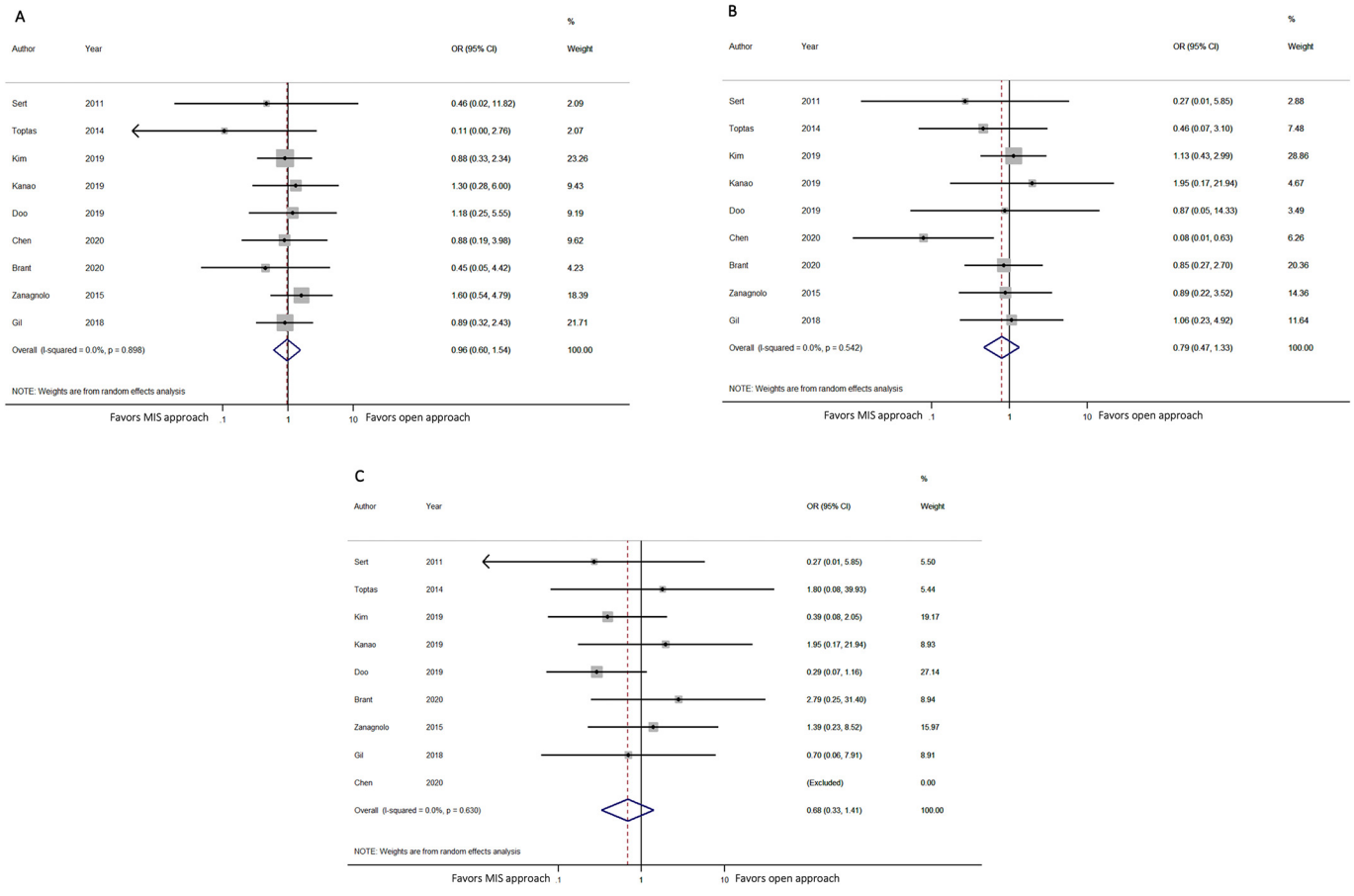

Fig. 2. A Forest plot showing pooled odd ratio (OR) of local recurrence.
B Forest plot showing pooled odd ratio (OR) of distant recurrence.
C Forest plot showing pooled odd ratio (OR) of both locations.

In our opinion, our results could be generalizable if we consider the specific clinical setting of patients with stage IB1 cervical cancer. However, we believe that these results cannot be extrapolated to the entire population of cervical cancer patients undergoing radical hysterectomy as primary treatment.

Considering the above issues, we think that there is still a need for a large prospective observational study to determine the pattern of relapse in patients with tumors smaller than 4 cm. and to consider other factors that may modify the likelihood and site of relapse in these patients.

5. Conclusions

There are no differences in patterns of relapse across surgical approaches in patients with stage IB1 cervical cancer undergoing radical hysterectomy as primary treatment. However, we should be cautious with these results, since the limited number and quality of studies and the small number of patients must be considered.

Author contributions

N.M., J.A. and J.M. contributed to the conceptualization and design of the study. Data analysis and interpretation were performed by N.M., J.N., and Y.R. Figure and table creation was performed by N.M. and J.N.

N.M., L.C., E.C., F.B. and J.V. participated in drafting or revising the manuscript and approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ygyno.2021.11.018.

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