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Comparison of one-catheter strategy versus conventional two-catheter strategy on the volume of radiological contrast and diagnostic coronary catheterization performance by transradial access: A systematic review and meta-analysis of randomized clinical trials

Comparación de la estrategia de catéter único versus la estrategia convencional de dos catéteres sobre el volumen de contraste radiológico y el rendimiento del cateterismo coronario diagnóstico por acceso transradial: una revisión sistemática y meta-análisis de ensayos clínicos aleatorizados

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Abstract

Background: *One-catheter strategy, based in multipurpose catheters, allows exploring both coronary arteries with a single catheter. This strategy could simplify coronary catheterization and reduce the volume of contrast administration, by reducing radial spasm. To date, observational studies showed greater benefits regarding contrast consumption and catheterization performance than controlled trials. The aim of this work is to perform the first systematic review and meta-analysis of randomized clinical trials (RCT) to adequately quantify the benefits of one-catheter strategy, with multipurpose catheters, over conventional two-catheter strategy on contrast consumption, and catheterization performance.* **Methods:** *A search in PubMed, CINALH, and CENTRAL databases was conducted to identify randomized trials comparing one-catheter and two-catheter strategies. The primary outcome was volume of iodinated contrast administrated. Secondary endpoints, evaluating coronary catheterization performance included: arterial spasm, fluoroscopy time, and procedural time.* **Results:** *Five RCT were included for the final analysis, with a total of 1599 patients (802 patients with one-catheter strategy and 797 patients with two-catheter strategy). One-catheter strategy required less administration of radiological contrast (difference in means [DiM] [95% confidence interval (CI)]; –3.831 mL [–6.165 mL to –1.496 mL], p = 0.001) as compared to two-catheter strategy. Furthermore, less radial spasm (odds ratio [95% CI], 0.484 [0.363 to 0.644], p < 0.001) and less procedural time (DiM [95% CI], –72.471 s [–99.694 s to –45.249 s], p < 0.001) were observed in one-catheter strategy. No differences on fluoroscopy time were observed.* **Conclusions:** *One-catheter strategy induces a minimal reduction on radiological contrast administration but improves*

coronary catheterization performance by reducing arterial spasm and procedural time as compared to conventional two-catheter strategy.

Key words: Coronary angiography. One-catheter strategy. Radial spasm. Iodinated contrast. Systematic review. Meta-analysis.

Resumen

Antecedentes: *La estrategia de catéter único permite explorar ambas coronarias con un solo catéter. Nuestro objetivo es realizar la primera revisión sistemática y meta-análisis de ensayos clínicos aleatorizados para cuantificar adecuadamente los beneficios de la estrategia de catéter único, con catéteres multipropósito, sobre la estrategia convencional de dos catéteres.* **Métodos:** *Se realizó una búsqueda en PubMed, CINALH y CENTRAL, identificando ensayos aleatorizados que compararan estrategias de un catéter y dos catéteres. El resultado primario fue volumen de contraste administrado. Los secundarios, que evaluaron el rendimiento del cateterismo, incluyeron: espasmo radial, tiempo de fluoroscopia y de procedimiento.* **Resultados:** *Se incluyeron cinco ensayos, totalizando 1,599 pacientes (802 con estrategia de un catéter y 797 con estrategia de dos catéteres). La estrategia de catéter único requirió menos contraste (diferencia-de-medias; –3.831 mL [–6.165 mL a –1.496 mL], p = 0.001), presentando menos espasmo radial (odds ratio, 0.484 [0.363 a 0.644], p < 0.001) y menos tiempo de procedimiento (diferencia-de-medias; –72.471 s [–99.694 s a –45.249 s], p < 0.001). No hubo diferencias en el tiempo de fluoroscopia.* **Conclusiones:** *La estrategia de catéter único induce una reducción mínima en la administración de contraste, pero mejora el rendimiento del cateterismo al reducir el espasmo radial y el tiempo de procedimiento en comparación con la estrategia convencional.*

Palabras clave: Angiografía coronaria. Estrategia de catéter único. Espasmo radial. Contraste yodado. Revisión sistemática. Meta-análisis.

Introduction

Coronary angiography is the "gold standard" technique for the diagnosis of coronary atherosclerosis. At present, the access of choice for coronary angiography is transradial access[1,2]. Despite the progressive reduction in coronary procedural complications that have occurred over time, the existence of complications persists and can generate serious consequences[1,2]. The administration of radiological contrast may lead to the development of adverse events such as contrast-induced nephropathy (CIN) or allergic reactions[3-5]. Furthermore, the induction of radial spasm is related with cross-over to transfemoral access and further vascular complications[6,7]. Traditional technique for coronary angiography, by transradial access, uses independent catheters for the cannulation of each coronary artery, inducing radial spasm and requiring additional fluoroscopy time and contrast injections for the correct engage of coronary ostia. Nevertheless, the performance of a coronary angiography with a one-catheter strategy by multipurpose coronary catheters, like TIGER catheters, could simplify procedures decreasing radial spasm, procedural time, and radiological contrast consumption, and currently, it is the usual practice to perform trans-radial coronary angiographies.

In recent years, multiple studies have been published about the benefits of the one-catheter strategy, highlighting greater benefit in observational studies[8-11] than in controlled studies[12-16], which may entail a bias in the perception of the real benefits of this strategy, especially regarding radiological contrast saving. However, to date there are no studies that integrate the information derived from randomized clinical trials (RCT) to adequately quantify the advantages of the one-catheter strategy.

Therefore, we performed the first systematic review and meta-analysis of RCT evaluating one-catheter strategy versus two-catheter strategy to compare the amount of iodinated contrast, the induction of radial spasm and fluoroscopy and procedural time, between these two strategies for coronary angiography by transradial access.

Methods

Search strategy, endpoints, and data extraction

Two reviewers (DFR and JCM) independently searched PubMed, CINALH, and CENTRAL databases until November 2017. To be included, published studies should be randomized comparisons between one- and
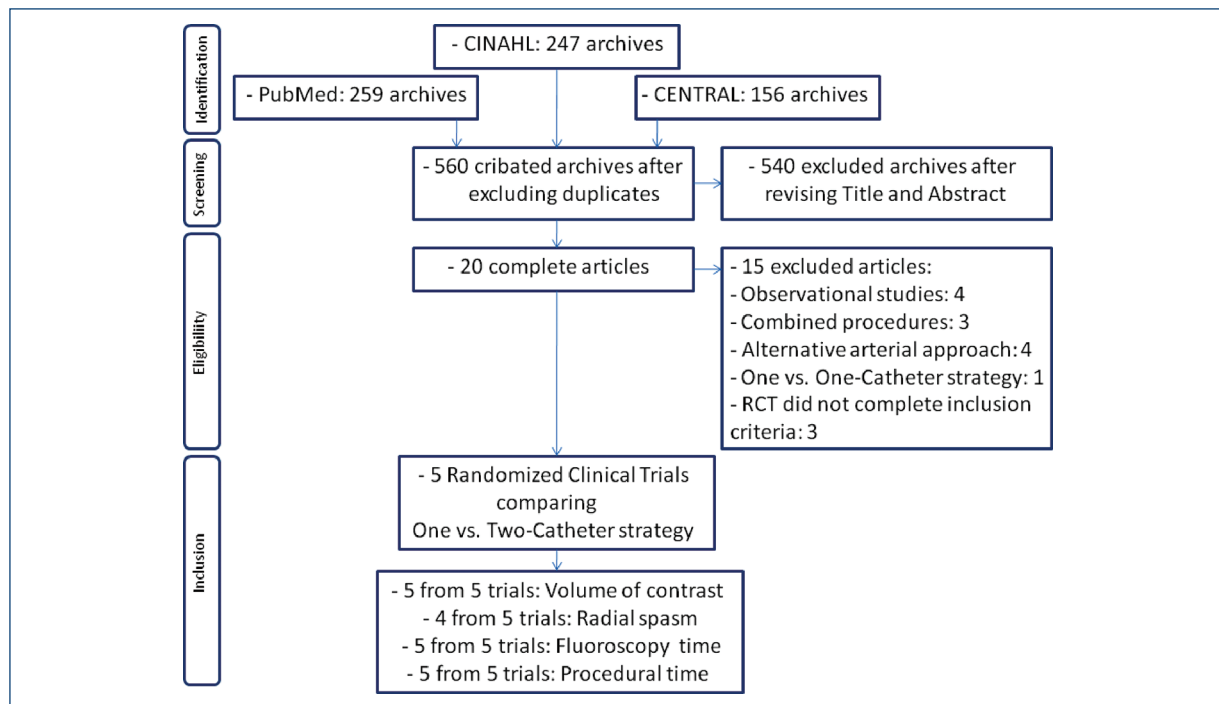
Figure 1. Flow-chart representing bibliographic search and identification of primary studies.

two-catheter strategies for diagnostic coronary angiography. Furthermore, articles had to report on the primary endpoint of our investigation and should be written in English language. The following terms or keywords were used: (one-catheter odds ratio [OR] single catheter OR TIGER catheter OR multipurpose catheter) AND (coronary angiography OR cardiac angiography) AND (controlled study OR randomized study OR RCT). Reference lists of included studies were scanned to retrieve additional relevant studies.

Primary endpoint was total volume of contrast administrated in coronary procedures. Secondary endpoints, evaluating coronary catheterization performance, included radial spasm (definitions according to each study in the Supplementary Material: Table 1), fluoroscopy time, and total procedural time.

RCT were selected if included information about volume of iodinated contrast and the following items were extracted from each selected article: year of publication, type of study design, type of catheter used, number of operators, sample size, total volume of contrast (mL), presence of radial spasm, fluoroscopy time (sec), total procedural time (sec), and baseline clinical characteristics. The authors of the original studies were not required to expand the information referred to such

works. Disagreements regarding inclusion or exclusion criteria were resolved by consensus (Fig. 1).

Statistical analysis

These systematic review and meta-analysis were conducted in accordance with the criteria reported in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) consensus document (PRISMA)[17].

Statistical analysis and forest-plot diagrams were performed using the Comprehensive Meta-Analysis software (Biostat, Englewood, NJ, USA). Pooled difference in means (DiM) or OR were used as summary statistics. All p-values were two-tailed, with statistical significance set at 0.05. The results were presented with a 95% confidence interval (95% CI). The authors assessed statistical heterogeneity using the I^2 test. A fixed-effect model was used in absence of heterogeneity, and a random-effects model was used in case of detecting heterogeneity between studies (I^2 statistic > 50%). Therefore, a fixed-effect model was used for the radial spasm and a random-effects model for the other endpoints. Sensitivity analyses for primary endpoint were conducted excluding one trial at a time.

Assessment of study quality and publication bias

Two authors (JC and KR) evaluated the selected RCT studies to assess their quality and possible biases, and in case of discrepancies, they were resolved by consensus. The quality and possible biases of RCT were evaluated using the validated criteria of Juni[18]. For the primary endpoint (volume of contrast administered), the publication bias was assessed using the Egger's statistical test for publication bias and visual inspection of the funnel plot[19].

Results

In the literature review, a total of 670 articles were obtained. After reviewing all the titles and abstracts, 20 full-text articles were selected. Fifteen articles, from the total of selected articles, were excluded for the following reasons: four of them were observational studies, three articles informed about guiding catheters designed for combined procedures (diagnostic and therapeutic interventions), four papers were related with alternative arterial approaches to trans-radial access, and one article compared two types of universal dedicated catheters for right trans-radial approach in a one versus one-catheter strategy. It is noteworthy that three RCT comparing one versus two-catheter strategy were not included for the final analysis because one article did not inform about the primary endpoint of the study (volume of contrast administered)[20] and two articles were not written in English language[21,22] (Fig. 1). Finally, five studies met the inclusion criteria[12-16].

These five RCT contained data on 1599 patients. Eight-hundred two patients underwent to one-catheter strategy and 797 patients to two-catheter strategy. Tables 1 and 2 depict main characteristics of the studies. Quality of studies was also evaluated (Table 3).

Regarding to the total volume of contrast used, all five studies[12-16] were used for the pooled analysis. A significant difference was observed in the total volume of contrast administered favorable to one-catheter strategy (DiM [95% CI]; –3.831 mL [–6.165 mL-–1.496 mL], p = 0.001). A random-effects model was used because the presence of significant heterogeneity (I^2 test = 59.1%) (Fig. 2). Publication bias was not detected based on visual inspection of the funnel plot and Egger's regression test for small study effect. Volume of contrast comparison is provided as an example which showed symmetrical funnel plot (Supplementary Fig.1) and p = 0.35 for Egger's test. The sensitivity analysis by

Table 1. Design, type of multipurpose catheter, and endpoints of original randomized clinical trials

Study year	Design	Type of catheter	Operators (n)	1C (n)	2C (n)	Contrast (mL) Mean ± SD Median (IQR)		Radial spasm n (%)		Fluoroscopy (sec) Mean ± SD Median (IQR)		Procedural time (sec) Mean ± SD Median (IQR)	
						1C	2C	1C	2C	1C	2C	1C	2C
Turan et al. (2016)[12]	RCT	Judkins Left	3	103	103	50 ± 12	51 ± 13	13 (12.6%)	23 (22.3%)	157 ± 83	131±92	402 ± 126	474 ±198
Chen et al. (2016)[13]	RCT	TIGER II	7	57	53	48 ± 16	53 ± 19	3 (5.3%)	3 (5.7%)	184 ± 91	238 ± 131	337 ± 382	434 ± 137
Erden et al. (2017)[14]	RCT	Modified Judkins Left	2	194	193	49 ± 13	52 ± 18	22 (11.3%)	42 (21.7%)	120±138	138 ± 90	342 ± 186	372 ± 150
Tarighatnia et al. (2017)[15]	RCT	TIGER II	-	128	128	51 ± 12	54 ± 16	-	-	152 ± 83	203 ± 121	570 ± 192	684 ± 240
Xanthopoulou et al. (2017)[16]	RCT	TIGER II	10	320	320	67 (54-82)	73 (60-94)	52 (16.3%)	93 (29.1%)	121 (79-188)	134 (90-210)	331 (250-439)	411 (309-578)

RCT: randomized clinical trial; 1C: one-catheter strategy; 2C: two-catheter strategy; mL: milliliter; sec: seconds; SD: standard deviation; IQR: inter-quartile range. *Numerical data regarding iodinated contrast, fluoroscopy time and procedural time were rounded to the nearest unit to facilitate the understanding of the table.
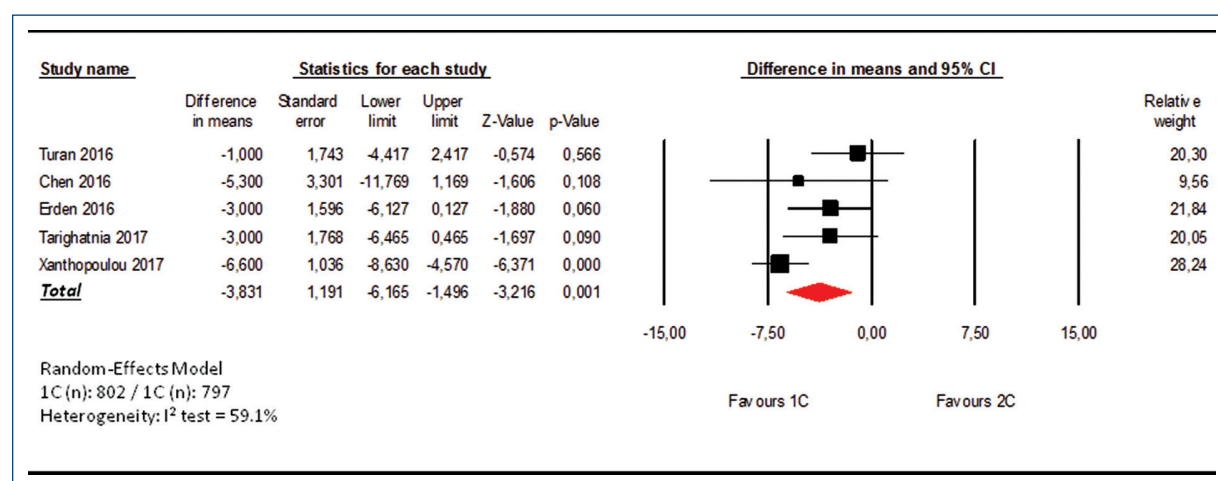
Table 2. Baseline clinical characteristics of original randomized clinical trials

		Turan et al. (2016)[12]		Chen et al. (2016)[13]		Erden et al. (2017)[14]		Tarighatnia et al. (2017)[15]		Xanthopoulou et al. (2017)[16]	
		1C (n = 103)	2C (n = 103)	1C (n = 57)	2C (n = 53)	1C (n = 194)	2C (n=193)	1C (n = 128)	2C (n = 128)	1C (n = 320)	2C (n = 320)
Age (Years), *Mean ± SD*		59.7 ± 13.6	61.0 ± 11.1	65.2 ± 12.7	67.5 ± 9.9	57.9 (12.9)	59.6 (13.1)	59.5 ± 11.5	59.2 ± 10.0	66.2 ± 11.4	66.4 ± 11.7
Sex female, n (%)		40 (38.8%)	36 (34.9%)	24 (42%)	17 (32%)	80 (41.2%)	76 (39.4%)	46 (35.9%)	46(35.9%)	91 (28.4%)	86 (26.9%)
BMI (Kg/m²), *Mean ± SD**		28.6 ± 4.9	28.9 ± 5.0	31.6 ± 7.7	30.9 ± 7.8	28.4	29.2	27.3 ± 4.8	27.7 ± 4.2	28.4 ± 4.8	28.4 ± 4.5
Medical history	Hypertension, n (%)	59 (57.3%)	61 (59.2%)	49 (86.0%)	42 (79.2%)	123 (63.4%)	126 (65.2%)	-	-	192 (60.0%)	193 (60.3%)
	Dyslipidemia, n (%)	36 (35.0%)	34 (33.0%)	44 (77.2%)	38 (71.7%)	84 (43.2%)	88 (45.5%)	-	-	170 (53.1%)	157 (49.1%)
	Diabetes, n (%)	39 (37.9%)	43 (41.7%)	20 (35.1%)	22 (41.5%)	66 (34.0%)	69 (35.7%)	-	-	86 (26.9%)	81 (25.3%)
	Smoker, n (%)	31 (30.1%)	33 (32.0%)	13 (22.8%)	6 (11.3%)	62 (31.9%)	59 (30.5%)	-	-	150 (46.9%)	144 (45.0%)
	Previous PCI, n (%)	31 (30.1%)	28 (27.2%)	-	-	56 (28.8%)	58 (30.0%)	-	-	-	-
Technical events	Supplemental catheter, n(%)	35 (34.0%)	1 (0.97%)	8 (14.0%)	0 (0%)	21 (10.8%)	5 (2.6%)	-	-	57 (17.8%)	68 (21.3%)
Severity of coronary artery disease	No disease, n (%)	33 (32.0%)	39 (37.9%)	-	-	71 (36.7%)	71 (33.5%)	-	-	164 (51.2%)	155 (48.4%)
	1 vessel disease, n (%)	39 (37.9%)	34 (33.0%)	-	-	69 (35.5%)	70 (36.2%)	-	-	79 (24.7%)	77 (24.1%)
	2 vessel disease, n (%)	20 (19.4%)	19 (18.4%)	-	-	32 (16.4%)	38 (19.6%)	-	-	42 (13.1%)	35 (10.9%)
	3 vessel disease, n (%)	11 (10.7%)	11 (10.7%)	-	-	22 (11.3%)	20 (10.3%)	-	-	35 (10.9%)	53 (16.6%)

1C: one-catheter strategy; 2C: two-catheter strategy; SD: standard deviation: BMI: body mass index. *SD in BMI was not reported in Erden article.

Table 3. Quality assessment for randomized clinical trials included in the systematic review (Juni Criteria)

Studies	Turan et al. (2016)[12]	Chen et al. (2016)[13]	Erden et al. (2017)[14]	Tarighatnia et al. (2017)[15]	Xanthopoulou et al. (2017)[16]
Selection					
1. Was allocation adequate? Mean-central site, numeric code, opaque envelopes, drugs prepared by pharmacy	Yes	Yes	Yes	Yes	Yes
2. Was an adequate method of randomization described?	Yes	Yes	Yes	Yes	Yes
3. Were groups similar at the start of the study?	Yes	Yes	Yes	Yes	Yes
Performance					
4. Were the patients/caregivers blinded to the intervention?	No	No	No	No	No
Detection					
5. Was the outcome ascertained blindly?	Yes	Yes	Yes	Yes	Yes
Attrition					
6. What percentage was lost at follow-up?	0%	0%	0%	0%	0%
7. Were all patients analyzed in the group to which they were assigned (intention-to-treat analysis)?	No	Yes	No	Yes	Yes

Figure 2. Forest-plot representing volume of contrast administrated. mL: Milliliters. CI: Confidence interval. 1C: One-catheter strategy. 2C: Two-catheter strategy.

excluding one study at a time did not change direction of the pooled effect sizes.

Four controlled trials[12-14,16] informed regarding radial spasm, including 674 patients in the 1C group and 669 patients in the 2C group. 1C group presented less induction of radial spasm (OR [95% CI]; 0.484 [0.363-0.644], p < 0.001). A fixed-effects model was used because the absence of heterogeneity (I^2 test = 0.0%) (Fig. 3).

In the analysis related to fluoroscopy time, all five RCT[12-16] were included for the analysis. No differences

were detected on fluoroscopy time was detected between groups (DiM [95% CI], –19.193 s [–41.425 s to –3.039 s], p = 0.091). It is noteworthy that a random effects model was performed to the significant heterogeneity (I^2 test = 82.3%) (Fig. 4).

All five randomized trials[12-16] informed regarding the total procedural time. A significant difference was observed (DiM [95% CI], –72.471 s [–99.694 s to-45.249 s], p < 0.001). Because the heterogeneity, a random effects method was used (I^2 test = 58.2%) (Fig. 5).
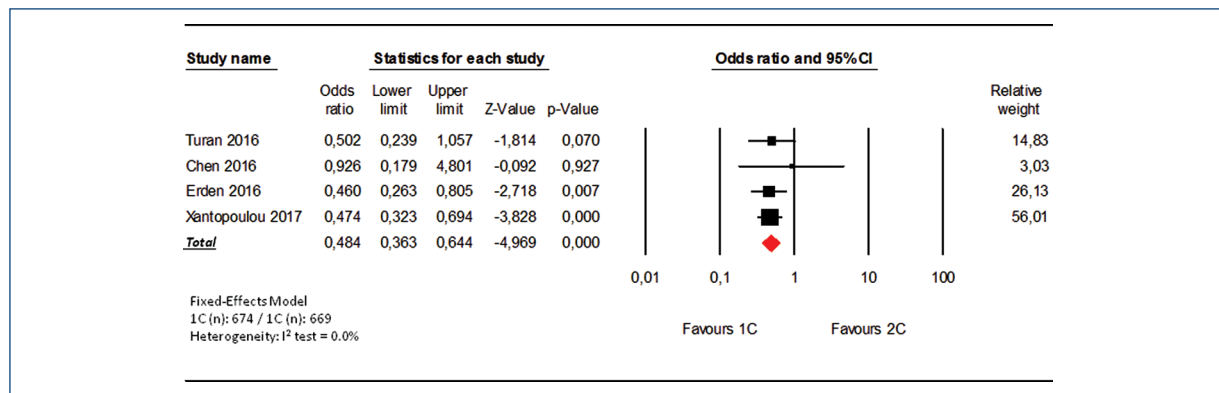
Figure 3. Forest-plot representing radial spasm. CI: Confidence interval. 1C: One-catheter strategy. 2C: Two-catheter strategy.

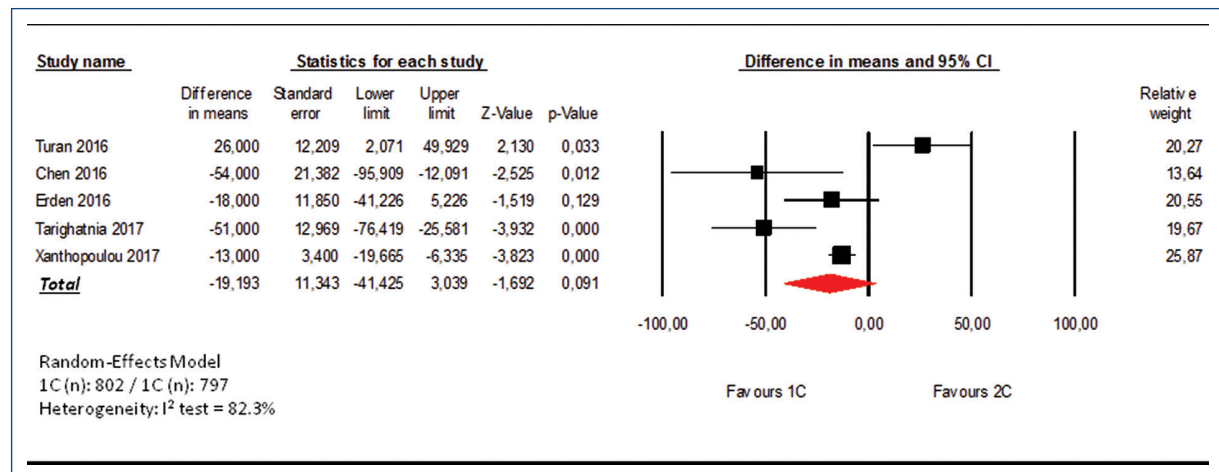**Figure 4.** Forest-plot representing fluoroscopy time. sec: Seconds. CI: Confidence interval. 1C: One-catheter strategy. 2C: Two-catheter strategy.

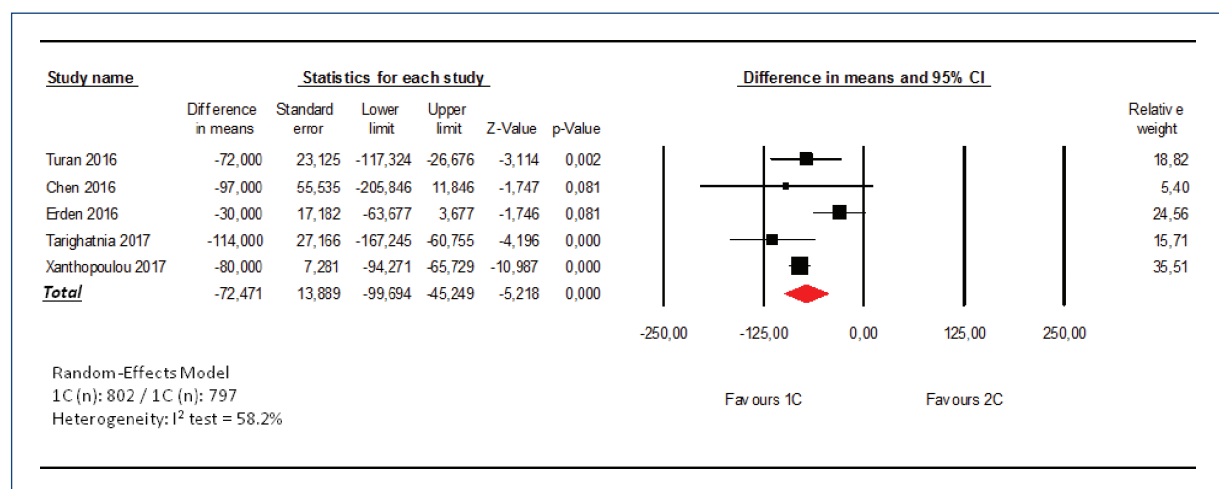**Figure 5.** Forest-plot representing procedural time. Sec: Seconds. CI: Confidence interval. 1C: One-catheter strategy. 2C: Two-catheter strategy.

Discussion

The main findings in our investigation were that of one-catheter strategy is associated with a minimal reduction in the volume of iodinated contrast used in coronary angiography procedures and a better performance in diagnostic coronary catheterization, evaluated as radial spasm and procedural time, in comparison with conventional two-catheter strategy.

Radiological contrast administration

One of main complications of invasive coronary procedures is the development of CIN. This condition could reach one-third of patients undergoing coronary procedures and is one of the more common causes of acute kidney injury in cardiological patients[3,4,23,24]. Furthermore, CIN is related with prolongation of the hospitalization, the death at short- and long-term[3,4] and increments in direct and indirect costs[25]. Because of the amount of iodinated contrast used in angiographic procedures is closely linked to CIN[26,27], the implementation of any technique that could reduce the administration of radiological contrast is very much appreciated by interventional cardiologists.

Pooled results show a consistent reduction in the primary endpoint of the study (volume of radiological contrast used in coronary diagnostic procedures). Nevertheless, the reduction in contrast administration is minimal in the joint analysis of RCT (DiM [95% CI]; −3.831 mL [−6.165 mL-−1.496 mL], p = 0.001). A recent observational study with a large number of patients observed a reduction in contrast administration, by one-catheter strategy, reaching 20 mL of radiological contrast[28]. However, the study of Langer et al.[28] could perhaps overestimate the effect of the one-catheter strategy on contrast saving, since it was an observational and retrospective study. This could also be motivated because in the participating centers, the standard catheter for performing coronary angiography in the usual clinical practice was the Tiger multipurpose catheter and the two-catheter strategy was used less frequently and this fact could penalize the two-catheter strategy.

The main finding of our study, which only analyzes randomized studies, is that the amount of contrast saved by the one-catheter strategy is very small. This fact implies that the preference of the one-catheter strategy over the two-catheter strategy at the time of performing coronary procedures would not be mediated by the supposed saving of radiological contrast but by other aspects related to the catheterization performance as we explain below.

Coronary catheterization performance

Radial spasm is a relatively common complication on transradial access with a variable incidence, ranging from 5% to 30%, depending on the definition[29-33]. Radial spasm induces patient discomfort and reduces procedural success[29,30]. In cases with need for conversion to transfemoral access is related with an increase in vascular complications[1,34].

Many factors, such as age, female gender, multiple radial punctures, and radial diameter are related with radial spasm.[6,7,30-32]. Furthermore, exchange of catheters during by transradial access has been linked to radial spasm induction, probably in relation to the repeated stimulation of the radial artery[6]. Likewise, the prolonged duration of coronary procedures may favor the development of arterial spasm and reduces patient comfort in trans-radial procedures, associating with greater probability of complications[6,7,30-32].

Our results show an important reduction in radial spasm (OR [95% CI], 0.484 [0.363-0.644], p < 0.001). Furthermore, one-catheter strategy produces a small reduction in procedural time (DiM [95% CI], −72.471 s [−99.694 s-−45.249 s], p < 0.001) in comparison with conventional strategy, but no significant differences between groups were detected on fluoroscopy time despite the favorable trend to one-catheter strategy (DiM [95% CI], −19.193 s [−41.425 s to −3.039 s], p = 0.091).

These facts make us hypothesize that one-catheter strategy, by reducing radial spasm development, simplifies the manipulation of coronary catheters resulting in slightly shorter times to complete diagnostic procedures and could decrease potential complications associated with radial spasm.

Limitations

The present study is limited by the presence of heterogeneity for some of the outcomes, which can be explained in part by the variation in the study design. However, random-effects models were used to mitigate this limitation if heterogeneity was detected. Due to lack of access to primary data, analyses based on patient characteristics regarding primary and secondary endpoints could not be performed. Nevertheless, our work is the first one performing a pooled analysis of RCT evaluating one-catheter strategy for diagnostic

coronary angiography which ensures the high quality of the studies included in the combined analysis.

Furthermore, individual studies included were not blinded to operators. This fact could influence operators regarding technical aspects like the final number of angiographical views, the fluoroscopy time or the total amount of contrast used. However, because the studies were protocolized randomized trials, the chances that the lack of blinding of the studies could affect the results are minimized.

Conclusions

One-catheter strategy for trans-radial coronary angiography induces only a minimal reduction on radiological contrast administration. Nevertheless, one-catheter strategy improves coronary catheterization performance, by reducing arterial spasm, and procedural time, as compared to two-catheter strategy.

Conflicts of interest

None.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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