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Effect of needle diameter on pain during oocyte retrieval—a randomized controlled trial

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Objective: To study pain in women undergoing oocyte retrieval with a reduced needle (20/17 gauge) compared to a standard needle (16 gauge).

Design: Single-center randomized controlled trial.

Setting: Fertility clinic.

Patients: Women undergoing their first oocyte retrieval for in vitro fertilization or intracytoplasmic sperm injection.

Interventions: Oocyte retrieval with a reduced needle (20/17 gauge) or with a standard needle (16 gauge).

Main Outcome Measures: The primary outcome measure was intraoperative pain on an 11-point visual analogue scale (VAS). Secondary outcome measures included the following: dosage of fentanyl requested; pain at 5, 15 and 30 minutes after retrieval; and pain and analgesia until 4 days after retrieval.

Results: A total of 47 women were randomized for the reduced needle (RN) and 48 for the standard needle (SN). Pain scores were significantly lower during and after retrieval with the RN. During retrieval, mean VAS scores in the RN group were 4.3 versus 6.3 in the SN group. Pain remained significantly lower in the RN group after retrieval, with VAS-scores of 1.2 vs. 2.1 directly after retrieval, 0.0 versus 2.0 5 minutes after retrieval, and 0.0 versus 1.0 30 minutes after retrieval. In the RN group, three patients (6.4%) requested more fentanyl during the procedure, versus 16 (33.3%) in the SN group. A total of 79 patients submitted their follow-up questionnaire (response rate 83%). Pain on the first 2 days following retrieval was significantly less in the RN group, with VAS scores of 1.6 versus 2.4 in the SN group, and 1.2 versus 2.5. In line with this finding, fewer patients in the RN group took analgesia on the days after the procedure. This difference was statistically significant only on day 3.

Conclusion: Use of a thinner needle results in significantly and clinically relevant lower pain scores during oocyte retrieval, and patients in the reduced needle group requested significantly less analgesia during oocyte retrieval than patients in the standard needle group. Pain scores remained significantly lower up until 2 days after the procedure.

Dutch Trial Registration Number: NTR6064 (www.trialregister.nl). (Fertil Steril® 2021;115:683–91. ©2020 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.

Key Words: Oocyte retrieval, pain, needle diameter, IVF, ICSI

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Ultrasound-guided oocyte retrieval is an essential part of in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) treatment. Even though oocyte

retrieval is a safe and efficient procedure, it is considered the most stressful and painful component of the IVF/ICSI process (1). Several methods of analgesia and sedation have been

described for oocyte retrieval, varying from general anesthesia to a paracervical block, and acupuncture, but conscious sedation seems to be the most frequently used method for pain relief (2, 3). In a Cochrane Review by Kwan et al. (4), studies comparing conscious sedation to other methods of pain relief in means of intra- and postoperative pain were analyzed, but no one method was proved to be superior to another.

Despite the large number of oocyte retrievals performed daily worldwide,

Received January 10, 2020; revised June 3, 2020; accepted June 22, 2020; published online October 16, 2020.

E.T.I.A.B. has nothing to disclose. J.P.d.B. has nothing to disclose. D.D.M.B. has nothing to disclose. J.W.v.d.S. has nothing to disclose.

Support provided by Vitrolife (Sweden) via an unrestricted grant. Vitrolife did not interfere or participate in the trial in any way.

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Fertility and Sterility® Vol. 115, No. 3, March 2021 0015-0282/\$36.00

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<https://doi.org/10.1016/j.fertnstert.2020.06.040>

little attention has been paid to nonpharmacological factors influencing pain. Optimizing the effect of other factors influencing pain during this procedure may result in better pain management overall. In particular, technical factors such as needle diameter have largely been neglected. So far, four studies have been published in which pain experience in relation to needle diameter was explored (5–8). In these studies, needles of 15, 16, 17, 18, and 20 gauge were used. In all studies, patients experienced less pain when the thinner needle was used. Concerns that thinner needles may damage the oocyte, compromising oocyte quality, were also assessed. A reduction in the diameter had no negative effect on oocyte quality, fertilization rate, or treatment outcome. However, there is considerable heterogeneity among the four studies. Different primary outcome measures for pain perception were used: the 11-point visual analogue scale (VAS), the 6-point VAS, and a verbal analogue scale. Furthermore, analgesia protocols and inclusion criteria in these studies differed significantly. Finally, recovery after the procedure was not assessed. This impairs a trustworthy comparison of the results of these studies, and translation to clinical settings. Therefore, we designed a randomized controlled trial to evaluate the effect of needle diameter on pain during oocyte retrieval, and recovery up until 4 days after oocyte retrieval.

MATERIALS AND METHODS

A randomized controlled trial was conducted at the fertility clinic of the Jeroen Bosch hospital in 's-Hertogenbosch, the Netherlands. Patients were enrolled from January 2017 to September 2018. The trial was registered in the Dutch trial registry as NTR6064 (www.trialregister.nl), and approval was obtained from the medical ethics committee. All participants provided informed consent.

Study Population

Women between 18 and 43 years of age who were undergoing their first oocyte retrieval for IVF or ICSI were eligible for inclusion. Exclusion criteria were having previously undergone oocyte retrieval or follicle reduction after ovulation induction or mild ovarian hyperstimulation treatments, severe endometriosis (grades III–IV), a body mass index of $>35 \text{ kg/m}^2$, standard use of analgesia, and a history of extensive surgery in the lower abdomen. Eligible patients were counseled by their doctors or by a specialized research nurse.

Ovarian Hyperstimulation

Patients underwent ovarian hyperstimulation with follicle-stimulating hormone or human menopausal gonadotrophin, in a dosage adjusted according to age, antral follicle count, and, whenever applicable, ovarian response to previous stimulation. Pituitary suppression was achieved with a GnRH-agonist or with a fixed start GnRH-antagonist protocol. Oocyte retrieval was planned when at least two follicles with a diameter of $>18 \text{ mm}$ had developed. Ovulation was induced by 10,000 IU hCG or by 6,500 IU choriogonadotropin alfa.

Randomization

Patients were randomized for oocyte retrieval with use of either a 20/17-gauge (0.9/1.4-mm) needle (Sense, Vitrolife; reduced needle [RN]) or a 16-gauge (1.6 mm) needle (Origio, CooperSurgical; standard needle [SN]). The 20/17-gauge needle has a tip with a 20-gauge diameter and a base with a 17-gauge diameter. The tip is used to puncture the tissue, whereas the base stabilizes the needle during the procedure.

A locally installed program was used to produce a block-randomization key with block sizes of four. This key was used to develop sealed opaque envelopes for the randomization process. Each envelope was numbered in ascending order. On the day of the last ultrasound before the oocyte retrieval, a nurse randomized the patient by opening the next available envelope. Patients and their partners were blinded to group allocation. For practical reasons, medical personnel could not be blinded.

Oocyte Retrieval

Cumulus–oocyte complexes were recovered by transvaginal ultrasound–guided retrieval 35–36 hours after hCG administration. One hour before the procedure, patients self-administered oxazepam 10 mg orally, paracetamol 1000 mg orally, and a diclofenac 100-mg suppository. Immediately before the procedure, they received fentanyl 50 μg intravenously, which could be increased by 25 μg up to two times during the procedure, upon the patient's request. A negative aspiration pressure of 120 mm Hg was used with both needles.

Immediately after the retrieval, the physician performing the procedure completed a form on which the following data were registered: total dosage of fentanyl administered, whether administration of atropine was needed to prevent or treat a vasovagal reaction to the procedure, the duration of the retrieval in minutes, whether obstruction of the needle had occurred, and the amount of blood loss. Blood loss was reported as “less than normal,” “normal,” or “more than normal.”

In Vitro Fertilization/Intracytoplasmic Sperm Injection

Both IVF and ICSI were performed in a transport setting. The follicular fluid collected during oocyte retrieval was transported to the IVF laboratory of the Elisabeth TweeSteden Hospital in Tilburg by the patient's partner. IVF and ICSI were carried out according to local protocol. Fresh embryo transfer was performed on day 3 after oocyte retrieval. In all women <38 years of age, one embryo was transferred. In women ≥ 38 years of age, one or two embryos were transferred depending on availability and the couple's preference. The other embryos were cryopreserved on day 4 or 5, depending on the quality.

Outcome Measures

Pain scores were assessed with use of an 11-point visual analogue scale (VAS), with 0 representing no pain, and 10 representing the worst imaginable pain. This was assessed

at four set moments on the day of retrieval: right before starting the procedure; immediately after the procedure, at which time the patients were asked about the pain during the procedure, and the current pain score; after 5 minutes; and 30 minutes after the procedure. In addition, patients kept a diary on the 4 days following the retrieval. The diary consisted of a questionnaire for each day on VAS pain scores twice daily, immediately after waking up, and before going to sleep, the effect of pain on daily activities, and physical exercise and analgesia use (type and dose). The primary outcome measure was pain during oocyte retrieval. All other measurements were secondary outcome measures.

Other secondary outcome measures were treatment outcomes: namely, the number of follicles, number of oocytes, retrieval rate (defined as the percentage of oocytes retrieved out of the available follicles), as well as the number of embryos available for fresh transfer and cryopreservation. Pregnancy outcomes of the fresh embryo transfer, 3 days after the retrieval, were registered. Pregnancy was defined as biochemical when a positive pregnancy test result occurred, without any other clinical signs of pregnancy on an ultrasound before week 7. Miscarriage was defined as nonvitality on an ultrasound before 12 weeks of pregnancy, and ongoing pregnancy was defined as a vital, intrauterine pregnancy confirmed by ultrasonography at week 12.

Sample Size and Statistical Analysis

Based on a previous assessment at our hospital, we assumed the mean overall pain in the SN group during oocyte retrieval to be 7 cm on a VAS with a standard deviation of 1.5 cm. A reduction of 1 cm was expected in the RN group. To demonstrate this difference with an α of 0.05 and a β of 0.20, a total of 36 patients were required in each group. To account for possible drop-outs or patients lost to follow-up, the sample size was expanded by 10% to a total of 80 participants. During the study, the follow-up questionnaire was changed, because the numeric rating scale instead of the VAS was used in the first version. Because of this change, we needed to expand the total sample size by 13.

For comparison between the two groups, Fisher's exact test was used for dichotomous variables and the Mann–Whitney *U*-test for continuous variables. Univariate analyses were also performed to explore the relationship between demographics and outcomes. All significance tests were two-sided and conducted at the 0.05 significance level. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corporation). Demographic variables were expressed as mean and standard deviation (SD) if the data were normally distributed, as median and interquartile range (IQR) if the data were not normally distributed, or as frequency and percentage for nominal data.

RESULTS

Between January 2017 and August 2018, a total of 167 patients were identified as eligible for participation in this trial. Of these patients, 98 provided written informed consent. Three patients were excluded after informed consent, one

because of termination of the relationship, and two because of cycle cancellation due to a poor ovarian response. Finally, 95 patients were randomized; 47 were allocated to retrieval with the RN, and 48 were allocated to retrieval with the SN (Fig. 1).

Baseline characteristics did not significantly differ in both groups (Table 1). Age was not normally distributed. The median age was 34.8 years in the RN group (interquartile range [IQR] 30.4–37.1) and 31.0 years in the SN group (IQR 28.8–36.3). Needle obstruction occurred twice in the RN group and once in the SN group. After needle obstruction, a new SN needle was used to finish the procedure. These cases were included in the intention-to-treat analysis.

Outcomes During Oocyte Retrieval

Pain scores were significantly lower during and after retrieval with the RN, as displayed in Table 2 and Supplemental Figure 1. During retrieval, mean VAS scores were 4.3 (± 2.0) in the RN group versus 6.3 (± 2.5) in the SN group ($P < .001$). Scores remained significantly lower in the RN group after retrieval; the median VAS scores were 1.2 (IQR 0.0–2.2) versus 2.1 (IQR 1.0–4.0) immediately after retrieval ($P = .005$), 0.0 (IQR 0.0–1.0) versus 2.0 (IQR 0.0–4.5) 5 minutes after retrieval ($P < .001$), and 0.0 (IQR 0.0–1.0) versus 1.0 (IQR 0.0–2.5) 30 minutes after retrieval ($P = .001$) in the RN group versus the SN group, respectively.

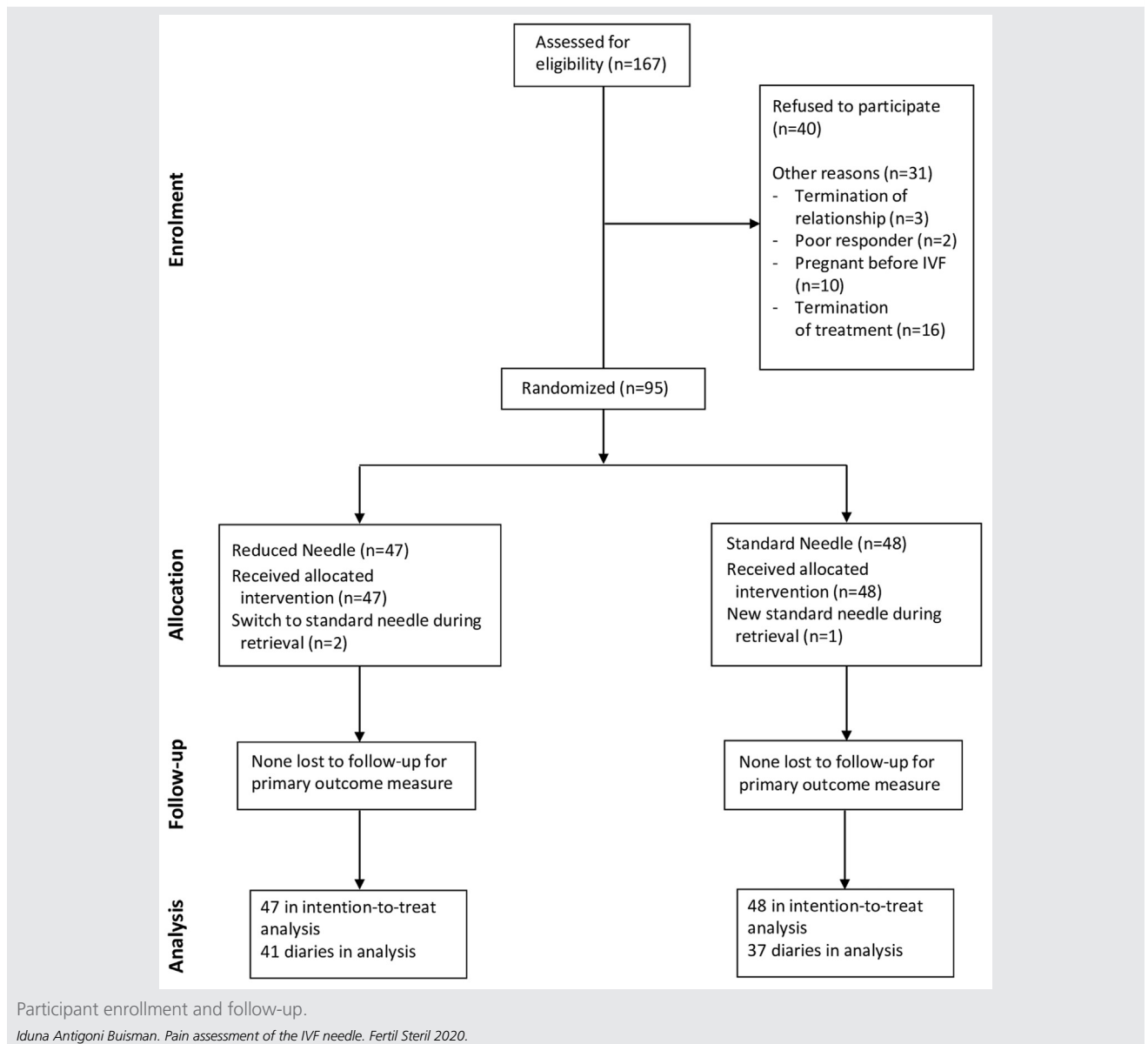
A significantly higher percentage of patients in the SN group requested more fentanyl intravenously. In the RN group, three of 47 patients (6.4%) requested an increase of medication at least once, versus 16 of 48 patients (33.3%) in the SN group (risk ratio [RR] 0.2, 95% confidence interval [CI] 0.1–0.6). None of the patients in the RN group requested a second increase, versus seven of 48 patients (14.6%) in the SN group.

Blood loss was rated as “less than normal” after 27 of 47 oocyte retrievals (60%) with the RN, versus 11 of 48 (22.9%) with the SN (RR 2.51; 95% CI 1.41–4.45), and as “more than normal” in 1 of 47 (2.1%) in the RN group, versus 9 of 48 (18.8%) in the SN group (RR 0.12; 95% CI 0.02–0.88). One of the 47 patients in the RN group (2.1%) experienced a vasovagal reaction after retrieval, for which atropine had to be administered, versus 5 of 48 (10.4%) in the SN group (RR 0.20; 95% CI 0.3–1.38).

Univariate Analyses

A number of univariate analyses were performed to detect factors of influence on pain scores. These were as follows: age, body mass index, ethnicity, education level, infertility diagnosis, male factor infertility as a separate variable, parity, as well as nulliparity versus multiparity, presence of endometriosis, number of follicles present, number of oocytes retrieved, and physician performing the procedure. The only significant effect on pain scores was seen for the number of follicles present. This was a linear effect: for each extra follicle present, the observed pain score during retrieval was 0.07 points higher (95% CI 0.001–0.139).

FIGURE 1



Treatment Outcomes

Table 2 lists the treatment outcomes in both groups. In the RN group, the median number of follicles available for retrieval was of 12 (IQR 7.0–18.0), versus 13 (IQR 9.0–18.0) in the SN group. Of the available follicles, 12 (IQR 7.0–18.0) were punctured in the RN group, vs. 12 (IQR 9.0–16.0) in the SN group. In the RN group, the median number of oocytes retrieved was eight (IQR 5.0–12.3), versus 10 (IQR 7.3–13.0) in the SN group ($P=.10$). This amounts to a median of 66.7% (IQR 47.6–86.2) oocytes retrieved from available follicles in the RN group, versus 75.0% (IQR 60.0–92.1) in the SN group ($P=.29$). The difference between the medians of the recovery rate was -8.33 (95% CI $-15.4, 3.33$), and the effect size (r) was -0.11 , which indicates a small effect.

The number of available embryos was statistically similar in both groups: 2.0 (IQR 1.0–4.0) in the RN group, versus 4.0 (IQR 1.0–6.0) in the SN group ($P=.15$). In the RN group, the median percentage of oocytes that developed into embryos fit for transfer after fertilization was 36.4% (IQR 15.38–50.0), and in the SN group it was 31.7% (IQR 16.67–50.0) ($P=.99$).

Pregnancy Outcomes

Following the embryo transfer 3 days after the oocyte retrieval, ongoing pregnancy was established in nine of 47 patients (19.1%) in the RN group, versus 10 of 48 (20.8%) in the SN group (RR 0.9; 95% CI 0.4–2.1). In the RN group, 2

TABLE 1

Patient demographics.		
Variable	Reduced needle (n = 47)	Standard needle (n = 48)
Patient age, y	34.8 (30.4–37.1)	31.0 (28.8–36.3)
Body mass index, kg/m ²	23.2 (21.0–27.0)	23.3 (21.5–27.0)
Nulliparous, n (%)	35 (74.5)	38 (79.2)
Duration of subfertility, y	2.2 (1.8–3.5)	2.4 (1.8–3.3)
Total motile sperm count after processing, million/mL	1.4 (0.1–4.2)	1.7 (0.2–5.0)
Ethnicity (white), n (%)	38 (80.9)	35 (72.9)
Endometriosis (grade 1 or 2) n (%)	3 (6.4)	1 (2.1)
Diagnosis, n (%)		
Male factor	22 (46.8)	28 (58.4)
PCOS	5 (10.6)	8 (16.7)
Other ovulation disorder	7 (14.8)	7 (14.6)
Two-sided tubal pathology	5 (10.6)	1 (2.1)
Unexplained subfertility	11 (23.4)	11 (22.9)
Other	1 (2.1)	2 (4.2)
Multiple	4 (8.5)	9 (18.7)
Treatment, n (%)		
IVF	27 (57.4)	27 (56.3)
ICSI	20 (42.6)	21 (43.8)
Follicles, n	12 (7–18)	13 (9–18)
Pain before OR, VAS	0 (0.0–0.0)	0 (0.0–1.0)

Note: Data presented as median (interquartile range), unless specified otherwise. No significant differences were observed between groups, as tested with a Mann–Whitney *U* test or *t*-test, depending on the variable type. ICSI = intracytoplasmic sperm injection; IVF = In vitro fertilization; OR = oocyte retrieval; PCOS = polycystic ovarian syndrome; VAS = visual analogue scale.

Iduna Antigoni Buisman. Pain assessment of the IVF needle. Fertil Steril 2020.

of 47 (4.3%) patients had a miscarriage, versus 4 of 48 (8.3%) in the SN group (RR 0.5; 95% CI 0.1–2.6).

Follow-up Questionnaires

The results of the follow-up are displayed in [Supplemental Figure 1](#). Of the 95 included patients, 42 of the 47 patients in the RN group (89.4%), vs. 37 of the 48 patients in the SN group (77.1%), submitted the follow-up questionnaires (RR 1.16; 95% CI 0.96–1.39). Pain scores remained lower in the RN group on the 4 days following oocyte retrieval, as shown in [Figure 2](#) and [Supplemental Figure 1](#). The difference in pain scores was statistically significant on the mornings of days 1 and 2 after the retrieval, with VAS scores of 1.6 (IQR 0–2.6) in the RN group on day 1, versus 2.4 (IQR 0.9–5.0) in the SN group ($P=.04$), and 1.2 (IQR 0.0–2.5) in the RN group on day 2 versus 2.5 (IQR 0.4–3.8) in the RN group ($P=.03$).

A higher percentage of patients in the SN group reported an effect of the pain on daily activities on the 4 days following the procedure, but this difference was not statistically significant. More patients in the SN group used oral analgesics on all 4 days following the retrieval, but this difference was statistically significant only on day 3, on which three of 42 (7.1%) patients used oral analgesics in the RN group, versus 11 of 35 (31.4%) patients in the SN group (RR 0.23; 95% CI 0.07–0.75).

DISCUSSION

Pain scores during and after oocyte retrieval were compared after use of a reduced 20/17-gauge needle vs. our standard 16-gauge needle. Both during and after oocyte retrieval, pain scores were significantly lower after use of the RN when compared to the SN. Patients in the RN group requested

less fentanyl during the procedure. Recovery was also improved after retrieval with the RN: pain scores remained significantly lower in the morning of the 4 days following the procedure, fewer patients took oral analgesics, and fewer patients reported that the procedure had an effect on daily activities.

The mean pain score in our SN group is higher than the scores reported in most studies on pain during oocyte retrieval, with a mean VAS of 6.3 (SD \pm 2.5). Wikland et al. (2011) also compared pain on the VAS, after use of a 20/17-gauge and a 17-gauge needle, and reported a mean VAS of 2.14 (\pm 1.81) in the RN group, versus 2.60 (\pm 1.97) in the SN group (6). This difference is most likely explained by the differences in analgesia protocols. In the study by Wikland et al., fentanyl administered intravenously was combined with a paracervical block, which is more invasive than only fentanyl administered intravenously, as at our center. After use of the RN, significantly fewer patients reported severe pain during retrieval, defined as a VAS of 7 or higher (9). Only four of 47 (8.5%) patients in the RN group reported severe pain, vs. 20 of 48 (41.7%) in the SN group (relative risk 0.20; 95% CI 0.07–0.55) (Table 2). In line with this finding, less fentanyl was requested in the RN group. Therefore, use of the RN is an effective method to reduce pain as well as the need for analgesia. Occurrence of side effects as a result of fentanyl administration, such as dizziness or nausea, was not studied in this trial. However, it can be assumed that a lower dose of fentanyl causes fewer side effects, thereby further improving the experience after use of the RN.

Although previous studies have shown less pain during oocyte retrieval with a thinner retrieval needle, this is the first study comparing pain scores and other recovery parameters

TABLE 2

Pain scores and secondary outcome measures on the day of oocyte retrieval.

Variable	Reduced needle (n = 47)	Standard needle (n = 48)	P value
Pain during OR, mean VAS (\pm SD)	4.3 (\pm 2.0)	6.3 (\pm 2.5)	< .001
Pain during OR per category, n (%)			
Low (VAS 0.0–3.9)	18 (38.3)	7 (14.6)	2.63 (1.21–5.70) ^a
Moderate (VAS 4.0–6.9)	25 (53.2)	21 (43.8)	1.22 (0.80–1.85) ^b
Severe (VAS \geq 7.0)	4 (8.5)	20 (41.7)	0.20 (0.07–0.53) ^a
Pain directly after OR, VAS	1.2 (0.0–2.2)	2.1 (1.0–4.0)	.005
Pain after 5 min, VAS	0.0 (0.0–1.0)	2.0 (0.0–4.5)	< .001
Pain after 30 min, VAS	0 (0.0–1.0)	1.0 (0.0–2.5)	.001
Duration of OR, min	8.0 (5.0–10.5)	7.0 (5.0–10.0)	.24
Request for more fentanyl during OR, n (%)			
None	44 (93.6)	32 (66.7)	1.40 (1.13–1.74) ^a
At least once	3 (6.4)	16 (33.3)	0.19 (0.06–0.61) ^a
Twice	0 (0)	7 (14.6)	–
Rating of blood loss, n (%)			
Less than normal	27 (60.0)	11 (22.9)	2.51 (1.41–4.45) ^a
More than normal	1 (2.1)	9 (18.8)	0.12 (0.02–0.88) ^a
Need for atropine, n (%)	1 (2.1)	5 (10.4)	0.20 (0.03–1.68) ^b
Follicles present on day of OR, n	12 (7.0–18.0)	13 (9.0–18.0)	.23
Follicles punctured, n	12 (7.0–18.0)	12 (9.0–16.0)	.30
Oocytes retrieved, n	8 (5.0–12.3)	10 (7.3–13.0)	.10
Retrieval rate (% of oocytes retrieved from follicles present), %	66.7 (47.6–86.2)	75.0 (60.0–92.1)	.29
Embryos, n	2.0 (1.0–4.0)	4.0 (1.0–6.0)	.15
Ongoing pregnancy, n (%)	9 (19.1)	10 (20.8)	0.91 (0.41–2.06) ^b

Note: Data presented as n (%) or median (IQR), unless stated otherwise. Power calculation was done with Mann–Whitney U test. CI = confidence interval; IQR = interquartile range; OR = oocyte retrieval; SD = standard deviation; VAS = visual analogue scale.

^a Relative risk (95% confidence interval): were statistically significant.

^b Relative risk (95% confidence interval): were not statistically significant.

Iduna Antigoni Buisman. Pain assessment of the IVF needle. *Fertil Steril* 2020.

on the days following oocyte retrieval. We assessed both objective as well as subjective measures of pain until after the day of the embryo transfer. Interestingly, the use of a thinner needle is associated with reduced pain for several days after the procedure. This may be explained by a reduction in tissue trauma with the thinner needle tip, although it might also be the result of a less painful experience of the retrieval itself. Significantly fewer patients in the RN group used oral analgesics on day 3 after the retrieval (3 of 42 [7.1%]) versus 11 of 35 [31.4%]; RR 0.23; 95% CI 0.07–0.75). Day 3 is the day of the embryo transfer at our clinic. A likely explanation is the assumption that the SN causes more tissue trauma, which makes manipulation during the embryo transfer more painful.

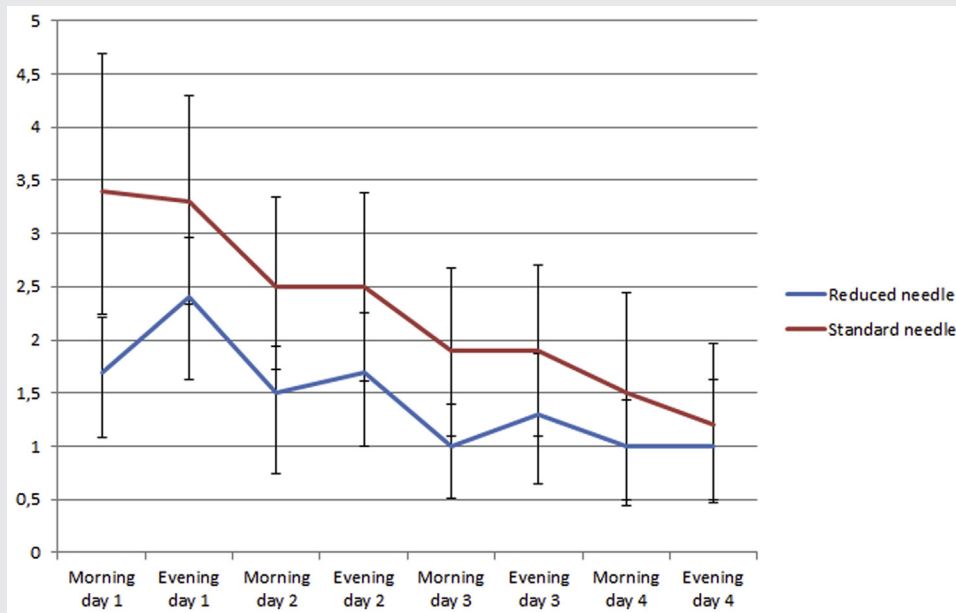
Our results show lower pain scores on the days following retrieval, and fewer patients using analgesia, although this difference was not statistically significant on all days. However, the study was not powered for this study outcome. Likewise, the rate of oocytes retrieved from available follicles was lower in the RN group (median 66.7% vs. 75.0%), as was the median number of embryos available in the RN group (2.0 vs. 4.0), but these differences were not statistically significant. Wikland et al. (6) observed more similar retrieval rates between the reduced needle and the standard needle. However, the standard needle used in their study had a slightly smaller

diameter of 17 gauge. A larger study is necessary to explore these outcomes further.

To study the relationship between the needle diameter and the quality of the oocytes and the embryos, we calculated the percentage of oocytes that developed into embryos fit for transfer after fertilization. This was similar in both groups. These findings, the similar number of embryos available for transfer per group, and the similar ongoing pregnancy rate in both groups supports that the needle diameter does not affect oocyte and embryo quality.

A limitation of this study was that many follow-up questionnaires were filled out incompletely. In an attempt to further objectify recovery, the follow-up questionnaire included questions on whether patients could go to work or engage in sports, and if so, the intensity at which they could work or exercise. The intensity was to be graded in percentages: 25%, 50%, 75%, or 100%. Unfortunately, of the 79 of 95 (83.2%) patients who submitted their questionnaire, only 39 of 79 (49.4%) answered all these questionnaires completely. Therefore, we did not consider the conclusions based on these results to be representative of the trial population. It is unknown why patients were inconsistent in filling out the questionnaire, but we suspect ineffective formulation of these specific questions. For future research on pain and recovery after oocyte retrieval, we recommend using

FIGURE 2



Pain on the days after oocyte retrieval, measured twice daily. Whiskers display 95% range. RN = reduced needle; SN = standard needle; VAS = visual analogue scale.

Iduna Antigoni Buisman. Pain assessment of the IVF needle. *Fertil Steril* 2020.

standardized and validated recovery questionnaires, such as the Quality of Recovery–40 scale (10).

Another limitation was the fact that this study was not double-blind; hospital personnel were not blinded to group allocation. Because of the shape of the needle, it was impossible for the nurse and physician performing the retrieval to be blinded. Physicians may particularly have been biased in their judgment of the amount of blood loss due to the knowledge of group allocation, but the outcome of pain scores may have been biased as well. To avoid this, a third person could have been used as a blinded outcome assessor, to ask about the VAS scores. However, to reduce recall bias, we considered it to be more important to assess the pain scores within 1 minute after the procedure. An outcome assessor would have to be present during the retrieval to achieve this, which was impractical. Physicians were instructed to always formulate the question about pain during the retrieval in the same way, and the patient was given the VAS to score the pain herself. Most importantly, patients and their partners were blinded to group allocation, reducing the greatest source of bias.

An important wider implication of these results is that use of a thinner needle may reduce costs of the IVF/ICSI treatment overall. The RN is currently more expensive than the SN used in this study; the RN costs €49.30 (\$55.39), whereas the SN costs €20.40 (\$22.81). Worldwide, conscious sedation seems to be the most frequently used method of analgesia during oocyte retrieval (2–4). However, the results of this study show very acceptable pain scores during the procedure with minimal analgesia. As shown in Table 2, most patients (44

of 47 [91.5%]) experienced low to moderate pain in the RN group. When comparing this method to conscious sedation, it is likely that costs are lower, because of a reduction in medication, a shorter procedure time, a shorter observation time, and fewer personnel needed. Although a formal cost-effectiveness study comparing the intravenous administration of opioids alone to conscious sedation has not yet been conducted, our results show that use of a thinner needle in combination with our relatively mild analgesia protocol can be a low-cost alternative to conscious sedation to achieve low to moderate pain scores. In light of the current COVID-19 pandemic, fewer personnel required during the procedure, as well as a reduction in the duration of observation in the hospital, can be additional advantages to increase the number of procedures that can be performed daily without consuming scarce hospital facilities.

CONCLUSION

In this study, a thinner needle was significantly associated with less pain during and up until 4 days after oocyte retrieval. Furthermore, significantly less fentanyl was needed during the procedure, and fewer patients took oral analgesics on the days following the procedure. Treatment outcomes were similar in both groups. Use of a thinner needle is an effective method to reduce pain and analgesics during oocyte retrieval.

Acknowledgments: We thank the staff of the Center for Reproductive Health at the Jeroen Bosch Hospital for all their efforts regarding this trial.

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Efecto del diámetro de la aguja en el dolor durante la punción ovárica: un estudio aleatorizado controlado.

Objetivo: estudiar el dolor en mujeres sometidas a una punción ovárica con una aguja más fina (calibre 20/17) o con una aguja convencional (calibre 16).

Diseño: Estudio aleatorizado y controlado en un único centro.

Entorno: Clínica de infertilidad.

Pacientes: Mujeres sometidas a su primer ciclo de fecundación in vitro o de inyección intracitoplasmática de espermatozoides.

Intervención: Punción ovárica con una aguja más fina (calibre 20/17) o con una aguja estándar (calibre 16).

Medidas de resultado principal: La principal medida fue el dolor intraoperatorio en una escala análoga visual (VAS). Las medidas de resultados secundarias fueron las siguientes: dosis necesarias de fentanilo, dolor a los 5, 15 y 30 minutos tras la punción, y el dolor y los analgésicos tomados hasta el 4^o día tras la punción.

Resultados: Se aleatorizaron un total de 47 mujeres en el grupo de aguja más reducida (RN) y de 48 en el grupo de aguja estándar (SN). Las puntuaciones de dolor durante y tras la punción ovárica fueron significativamente menores en el grupo RN. Durante la punción, las puntuaciones VAS medias fueron 4.3 en el grupo RN versus 6.3 en el grupo SN. El dolor se mantuvo significativamente más bajo en el grupo RN tras la punción, con unas puntuaciones VAS de 1.2 vs. 2.1 justo después de la punción, de 0.0 versus 2.0 a los 5 minutos postpunción y de 0.0 versus 1.2 a los 30 minutos postpunción. En el grupo RN, tres pacientes (6.4%) requirieron más fentanilo durante el procedimiento, frente a 16 (33.3%) en el grupo SN. Un total de 79 pacientes enviaron el cuestionario de seguimiento (tasa de respuesta del 83%). El dolor durante los primeros 2 días tras la punción fue significativamente menor en el grupo RN con puntuaciones VAS de 1.6, frente a 2.4 en el grupo SN y 1.2 versus 2.5. En línea con estos hallazgos, menos pacientes tomaron analgésicos los días tras la punción en el grupo RN. Esta diferencia sólo fue significativa en el día 3.

Conclusion: es: El uso de una aguja más fina conlleva unas menores puntuaciones de dolor durante la punción ovárica significativa y clínicamente relevantes y las pacientes en el grupo de aguja más fina requirieron significativamente menos analgesia durante la punción ovárica, comparadas con las pacientes del grupo de aguja estándar. Los valores de dolor se mantuvieron significativamente menores hasta 2 días después de la intervención.

Número de estudio del registro holandés: NTR6064 (www.trialregister.nl)