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## Paracervical Block for Intrauterine Device Placement Among Nulliparous Women: A Randomized Controlled Trial

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### Abstract

**Objective:** To investigate if 20 cc buffered 1% lidocaine paracervical block decreases pain during intrauterine device (IUD) placement.

**Methods:** In a randomized, single-blind, placebo-controlled trial, women were assigned to receive either 20 cc buffered 1% lidocaine paracervical block or no block prior to IUD placement. The primary outcome was pain with IUD placement measured on a 100 mm visual analog score (VAS). Our sample size had 80% power ( $\alpha=0.05$ ) to detect a 20 mm difference in VAS scores with a standard deviation of 28 mm. Secondary outcomes included pain with speculum placement, paracervical-block administration, tenaculum placement, 5 minutes post-procedure, and overall pain perception.

**Results:** From October 7, 2014, through October 26, 2017, 64 women were enrolled and analyzed (33 in paracervical-block arm, 31 in no-block arm). There were no differences in baseline demographics between the groups. Women who received the paracervical block reported less pain with IUD placement compared to women who received no block (median VAS score of 33 mm compared with 54 mm,  $p=0.002$ ). Pain was significantly less in the intervention group for uterine sounding (30 mm compared with 47 mm,  $p=0.005$ ), 5 minutes after placement (12 mm compared with 27 mm,  $p=0.005$ ) and overall pain perception (30 mm compared with 51 mm,  $p=0.015$ ). Participants who received the paracervical block experienced more pain with block administration compared to placebo (30 mm compared with 8 mm,  $p=0.003$ ). There was no perceived-pain difference for speculum insertion (10 mm compared with 6 mm,  $p=0.447$ ) or tenaculum placement (15 mm compared with 10 mm,  $p=0.268$ ).

**Conclusion:** A 20 cc buffered 1% lidocaine paracervical block decreases pain with IUD placement (primary outcome), uterine sounding (secondary outcome), and 5 minutes after

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placement (secondary outcome). While paracervical block administration can be painful, perception of pain for overall IUD placement procedure is lower compared to no block.

### **Precis:**

Paracervical block decreases pain with intrauterine device placement among nulliparous women..

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## **Introduction**

Intrauterine devices (IUDs) are long-acting reversible contraceptives with a failure rate less than 1%.<sup>1</sup> While IUD usage is increasing, it is still less commonly used compared to less effective methods including pills and condoms.<sup>2,3</sup> While IUD placement is an office procedure, fear of pain can be a barrier. This is especially a concern for nulliparous women, who experience more pain with placement compared to multiparous women.<sup>4,5</sup>

Currently, there is no standard of care for pain management with IUD placement among adult nulliparous women. The majority of randomized controlled trials of oral and local anesthetics have not demonstrated a reduction in pain scores with IUD placement.<sup>4-15</sup> If effective, use of a local anesthetic during the IUD placement would be convenient as it would not interrupt clinic flow.

Providers often suggest paracervical block with IUD placement among nulliparous women. A previous trial evaluating a 10 cc 1% lidocaine block did not demonstrate a decrease in pain with IUD placement.<sup>4</sup> However, the 10 cc block may not have been a sufficient dose, as studies for other types of gynecologic procedures have shown efficacy of a 20 cc block.<sup>16,17</sup> A trial utilizing a 10 cc 1% lidocaine block demonstrated a decrease in pain with IUD placement among nulliparous adolescents (14–25 years old) receiving the LNG-13.5 mg IUD (Skyla).<sup>18</sup> The LNG-52 mg and copper IUDs have slightly larger applicators, so it is difficult to extrapolate these results. This study evaluates if a 20 cc buffered 1% lidocaine paracervical block will decrease pain with IUD placement.

## **Materials and Methods**

Approval was obtained from the Institutional Review Board at University of California, San Diego. Nulliparous women 18 to 45 years of age presenting for an IUD placement for contraception or treatment of abnormal uterine bleeding were approached to participate in this study. Exclusion criteria included pregnancy, any diagnosed chronic pain issues (fibromyalgia, endometriosis, dysmenorrhea, irritable bowel syndrome, interstitial cystitis), use of pain medication (e.g., aspirin, NSAIDs) within 6 hours of enrollment, misoprostol administration within 24 hours of enrollment, history of prior IUD placement or known contraindications to IUD placement. Written informed consent was obtained. Each participant was randomly assigned to receive either a 20 cc buffered 1% lidocaine paracervical block or no paracervical block. We chose this buffered lidocaine because the sodium bicarbonate decreases the burning sensation associated with lidocaine administration.<sup>19</sup> We did not add vasopressin or epinephrine because IUD placements typically involve minimal risk for bleeding. Also, not including vasopressin or epinephrine makes the results more generalizable to clinics where these agents may not be available.

Randomization was performed utilizing a block size of 4 with group assignment via sequentially numbered, opaque, sealed envelopes. Given our smaller sample size, we chose a block size of 4 to ensure an equal distribution of participants who received the paracervical block and who did not receive the paracervical block. This study was single blinded to the participants. After group allocation, the clinician was informed to administer either the paracervical block or no paracervical block (a capped needle).

For the intervention group, we administered a 20 cc paracervical block that consisted of 18 cc of 1% lidocaine buffered with 2 cc 8.4% sodium bicarbonate. This block is most commonly reported in the literature.<sup>20–22</sup> After speculum insertion, 2 cc were injected at the tenaculum site superficially at 12 o'clock on the anterior lip of the cervix.<sup>23,24</sup> The tenaculum was placed at 12 o'clock. The remaining 18 cc was injected into the vaginal fornices equally at the 4 and 8 o'clock positions. The injection was continuous from superficial to deep (3cm) to superficial (injecting with insertion and withdrawal).<sup>21,22,25,26</sup> In the non-intervention group, the clinician performed a sham paracervical block as follows: 2 cc of buffered lidocaine were injected at the tenaculum site superficially at 12 o'clock on the anterior lip of the cervix, followed by tenaculum placement. Over 60 seconds, without moving the tenaculum, a capped needle gently touched the vaginal sidewall at the level of the external os at 4 and 8 o'clock. All participants were counseled during the no block or paracervical block and tenaculum placement using standardized language, e.g., "You may or may not feel something" to promote blinding. Placement of the IUD took place after application of the paracervical block or no block. The performing clinicians were obstetrics and gynecology attending physicians, resident physicians, and advance practice clinicians. We chose not to include a saline placebo block because the saline can distend the paracervical nerves and cause relief therefore it is not a true placebo. The capped needle approach is the same approach used by other paracervical studies.<sup>4,16,17</sup>

The outcome of interest was the participant's pain on a visual analog scale (VAS) from 0 mm (no pain) to 100 mm (worst pain imaginable) at various steps during the IUD placement. Participants marked the VAS scale for anticipated and baseline pain, pain during speculum insertion, sham or paracervical block administration, tenaculum placement, uterine sounding, IUD placement, 5 minutes after placement and overall pain.. VAS scores for anticipated and baseline pain were obtained just prior to the start of the procedure. VAS scores for speculum insertion, sham or paracervical administration, tenaculum placement, sounding, and IUD placement were obtained immediately following that step of the procedure. Participation concluded with a survey that included questions asking overall satisfaction with IUD placement and if they would recommend IUD placement to a friend using the same pain control (Box 1). This survey was used in prior pain control for IUD placement studies.<sup>4,14</sup> Participants were offered acetaminophen or ibuprofen at 5 minutes after the procedure. Participants received a \$10 gift card for participating.

The calculation of the sample size was based on previous studies involving pain control for IUD placement utilizing a 100 mm visual analog scale.<sup>4,5,15</sup> The standard deviation for pain with IUD placement was 23–35 mm in previous studies in the United States.<sup>4,12</sup> Our sample size calculation used a standard deviation of 28 mm. Prior studies have reported a range of 9–20mm as clinically significant differences in VAS pain scores. We defined a 20 mm

difference on the VAS as clinically significant. We chose the 20 mm difference in order to demonstrate a large enough difference to change clinical practice. Utilizing these parameters, we calculated that 64 participants would be required to achieve 80% power with a type I error ( $\alpha$ ) rate of 5% to detect this difference.<sup>27</sup> We planned recruitment of 67 participants to account for a 5% drop-out rate.

Data was analyzed with an intention to treat analysis. VAS pain scores were tested for normality utilizing the Shapiro Wilke test. The majority of VAS scores had a non-normal distribution, therefore median pain scores were compared using the Wilcoxon rank sum test. For demographics and questionnaires, chi-squared or Fisher exact tests were used to compare categorical variables and the *t* test or Wilcoxon rank sum tests were used to compare continuous variables. Statistical analyses were completed using SAS 9.4.

## Results

Recruitment occurred from October 2014 to October 2017 at the University of California, San Diego and Planned Parenthood of the Pacific Southwest. A total of 67 women were enrolled and 64 of those women completed the study. Three participants dropped out of the study because they were unable to tolerate the pelvic exam and did not want to proceed with IUD placement (Figure 1). There was no difference in baseline demographics including age, race or ethnicity, body mass index, or level of education between the two groups. There were 6 women in the paracervical block group and 1 in the no paracervical block group with prior abortions that were specified as terminations. None of the participants had more than one prior pregnancy. We do not have information on the type of termination (medical or surgical) or the trimester. No participants reported prior cervical procedures such as a conization (Table 1).

For the primary outcome of VAS score for IUD placement, the median pain score was less for the paracervical block group compared to the no paracervical block group (33 mm versus 54 mm,  $p = 0.002$ ). Median pain scores were also less for the secondary outcomes of uterine sounding (30 mm versus 47 mm,  $p = 0.005$ ), 5 minutes after IUD placement (12 mm versus 27 mm,  $p = 0.005$ ), and overall pain perception for the procedure (30 mm versus 51 mm,  $p < 0.05$ ). Pain with paracervical block administration was higher for the intervention group compared to the no paracervical block group (30 mm versus 8 mm,  $p = 0.003$ ). There was no difference in baseline pain, anticipated pain, pain with speculum or tenaculum placement (Table 2).

There was no difference in patient reported adverse effects. Participants in the no paracervical block group more often reported IUD placement pain was worse than expected pain (1.6% versus 14.1% for the paracervical versus no paracervical block group) while participants in the paracervical group more often reported no pain (10.9% versus 1.6%) or pain not as bad as expected (29.7% versus 18.8%) compared to the no paracervical block group (Table 3). There was no difference in the provider type, type of IUD inserted, purpose of IUD placement, uterine position, need for cervical dilation, or major complications reported by providers. There was also no difference in participants taking post procedural

ibuprofen or acetaminophen prior to leaving the office (Table 4). Of note, we were not powered to detect differences in these outcomes.

## Discussion

This study demonstrates that lidocaine administered locally via a paracervical block decreases pain with placement of the most commonly used IUDs, LNG 52 mg (Mirena) and CuT380A (Paragard). The study by Akers et al. showed a decrease in pain with 10 cc 1% lidocaine block, but had used the smaller LNG-13.5 mg (Skyla) IUD with adolescent participants who were 14–25 years old.<sup>18</sup> A phase II trial of lower-dose LNG IUDs demonstrated less pain associated with insertion of these smaller-framed IUDs compared to the LNG 52 mg IUD (Mirena).<sup>28</sup> Our study includes nulliparous women 18–45 years old receiving mostly the larger-framed LNG 52 mg and CuT380A IUDs, which are the most commonly utilized IUDs in the United States. Most of the IUDs included in our study provide the longer duration of use compared to the smaller, lower-dose IUDs. In addition, the LNG-52 IUD provides the highest likelihood of amenorrhea compared to the lower-dose LNG-IUDs.

Our sample size is powered to detect a 20 mm difference in VAS pain scores, which is consistent in being a clinically significant difference. This study provides more information for counseling about utilizing a lidocaine paracervical block and counseling nulliparous patients about pain and IUD placement. For example, the patient may be informed during counseling that the paracervical block typically does cause some pain (30 mm on a 100 mm scale), but that the paracervical block reduces pain with IUD placement, pain 5 minutes after the procedure, and perceived pain for the overall procedure.

Limitations of this study include the lack of diversity in age, race, and education level. The study had an under representation of African American participants compared to the national population, although representative of local demographics. Participants also tended to have higher education levels and were younger compared to the population of nationwide IUD recipients. These factors may limit the generalizability of the results. We also acknowledge that adding sodium bicarbonate may add a level of complexity to incorporating the results of this study into clinics that do not typically buffer the lidocaine. Another weakness of the study is that it did not include the newer LNG-52 mg IUD (Liletta®) that is now widely used. Although the LNG-52 mg IUD (Liletta®) was introduced nationally during the study period, it was not routinely offered at the study institutions during the recruitment period. Additionally the Liletta® IUD applicator is slightly larger than the Mirena or CuT380A (Paragard) IUD inserter, so investigators decided to exclude this IUD to avoid influencing pain scores.

Recruitment for this study took 3 years. A major challenge in recruitment was the exclusion criteria of ibuprofen and other pain medication use prior to IUD placement. While the literature does not support ibuprofen as effective analgesia for IUD placement, this study excluded women who used ibuprofen within 6 hours of study enrollment to eliminate any possible confounding effect of pain medications. However, since women are often told to

take ibuprofen by nurses or friends, this screened out many potential participants from the study.

Major strengths of this study include that it is a randomized controlled trial, use of the VAS, and utilization of a paracervical block technique comparable to other IUD-placement pain studies. This allows better comparison to other studies evaluating pain studies with IUD placement. We included both an academic site and the Planned Parenthood site in order to increase diversity of the participants. This was one of the first collaborative research studies between University of California, San Diego and Planned Parenthood of the Pacific Southwest. We also included a variety of clinician types including advance practice clinicians, residents, fellows, and Obstetrics and Gynecology attendings. This is one of the few studies to demonstrate an intervention that helps decrease pain with IUD placement and which should be offered to nulliparous women presenting for IUD placement.

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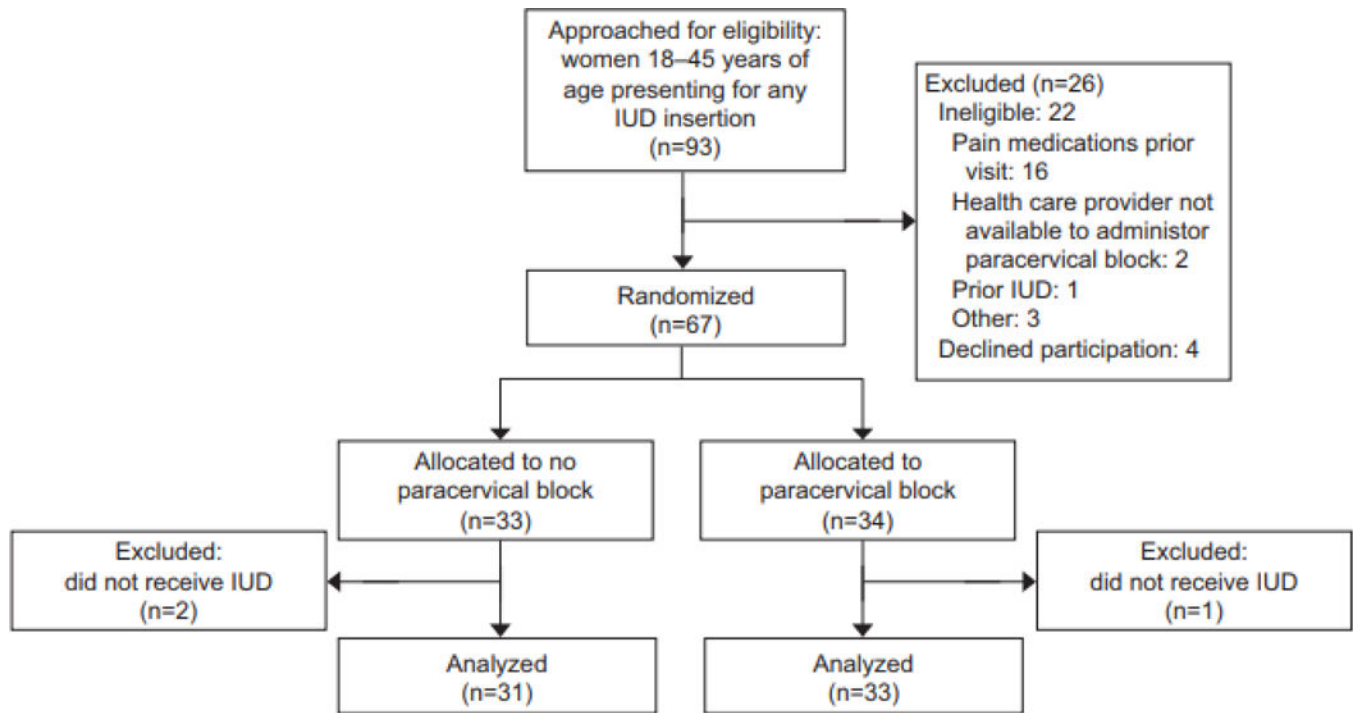
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**Box 1:****Post-IUD Insertion Patient Survey**

- 1. Did you experience any of the following side effects from the paracervical block? (circle all that apply)**
  - a. Nausea
  - b. Vomiting
  - c. Dizziness
  - d. Injection site pain? Please describe: \_\_\_\_\_
- 2. How would you describe the injection site pain?**
  - a. No injection pain
  - b. Not as bad as the IUD placement
  - c. Just as bad as the IUD placement
  - d. Worse than the IUD placement
  - e. Much worse than the IUD placement
- 3. How did the pain with IUD insertion compare to the expected pain?**
  - a. No pain with IUD insertion
  - b. Not as bad as the expected pain
  - c. Just as bad as the expected pain
  - d. Worse than the expected pain
  - e. Much worse than the expected pain
- 4. Are there are some things about the pain control you received that could be better?**
  - a. Yes
  - b. No
  - c. Not sure
- 5. Would you choose the same pain control method for a future IUD insertion?**
  - a. Yes
  - b. No
  - c. Not sure
- 6. Would you recommend this pain control method to a friend for IUD insertion?**



- a. Yes
- b. No
- c. Not sure



**Fig. 1.**  
Patient flow chart

**Table 1:**

## Demographics of study participants

	<b>No Paracervical Block (n=31)</b>	<b>Paracervical Block (n=33)</b>	<b>p-value</b>
<b>Age</b> , mean years (SD)	24.8±3.4	26.1±3.9	0.458 <sup>£</sup>
<b>Body mass index</b> , mean (SD)	24.0±5.9	24.5±4.4	0.089 <sup>£</sup>
<b>Ethnicity</b> -Non-Hispanic -Hispanic	23 (74.2) 8 (25.8)	26 (81.3) 6 (18.8)	0.556 <sup>€</sup>
<b>Race</b> - Caucasian - Black or African American - Asian or Pacific Islander - American Indian or Alaska Native - Other or multiracial	20 (64.5) 0 (0) 5 (16.1) 0 (0) 6 (19.4)	21 (67.7) 2 (6.5) 6 (19.4) 0 (0) 2 (6.5)	0.289 <sup>€</sup>
<b>Highest level of education completed</b> - High school graduate - Some college - College degree - Graduate degree	0 (0) 7 (22.6) 18 (58.1) 6 (19.4)	0 (0) 7 (21.1) 21 (63.6) 5 (15.2)	0.939 <sup>€</sup>
<b>Prior abortion</b>	1	6	0.106 <sup>€</sup>
<b>History of LEEP or conization</b>	0	0	1.000 <sup>€</sup>

Data are in mean (±SD) or n (%). Percent totals may not add up to 100 because of rounding.

<sup>£</sup> p value obtained from a t-test.

<sup>€</sup> p value obtained from a Fisher Exact test.

**Table 2:**

Median pain scores for all time points

	No Paracervical Block median (mm) [25%,75%] <sup>£</sup>	Paracervical Block median (mm) [25%,75%] <sup>£</sup>	Difference in pain scores	p-value*
<b>All participants</b>	<b>n = 31</b>	<b>n = 33</b>		
Anticipated pain	51 [30,70]	58 [48,68]	+7	0.419
Baseline pain	0 [0,2]	0 [0,2]	0	0.377
Speculum insertion	6 [2,20]	10 [4,14]	+4	0.447
Capped Needle or PCB	8 [2,20]	30 [17,47]	+22	0.0003
Tenaculum placement	10 [4,19]	15 [6,24]	+5	0.268
Uterine sounding	47 [24,65]	30 [8,43]	-17	0.005
IUD placement	54 [33,75]	33 [10,56]	-21	0.002
5 min after IUD placement	27 [15,50]	12 [6,27]	-15	0.005
Overall pain	51 [21,65]	30 [16,48]	-21	0.015

Pain scores reported in millimeters on a 0 to 100 mm visual analog scale.

Primary outcome of IUD placement is shaded in gray. All others are secondary outcomes.

\* p value obtained from a Wilcoxon rank sum test.

<sup>£</sup> Represents the interquartile range (25%, 75%).

**Table 3:**

Results of the participant survey completed at 5 minutes after IUD placement

	No Paracervical Block n = 31	Paracervical Block n = 33	p-value*
<b>Side effects</b>			
• Nausea	4 (6.3)	3 (4.7)	0.625
• Vomiting	0 (0)	0 (0)	1.0000
• Dizziness	8 (12.5)	10 (15.6)	0.689
• Injection site pain	11 (17.2)	19 (29.7)	0.077
<b>Injection site pain</b>			
• None	10 (32.3)	9 (27.3)	0.128
• Not as bad as the IUD placement	16 (51.6)	12 (36.4)	
• Just as bad as the IUD placement	4 (12.9)	3 (9.1)	
• Worse than the IUD placement	1 (3.2)	8 (24.2)	
• Much worse than the IUD placement	0 (0)	1 (3.0)	
<b>Pain with IUD placement compare with expected pain</b>			
• No pain with IUD placement	1 (3.2)	7 (21.2)	0.002
• Not as bad as expected pain	12 (38.7)	19 (57.6)	
• Just as bad as expected pain	5 (16.1)	6 (18.2)	
• Worse than expected pain	9 (29.0)	1 (3.0)	
• Much worse than expected pain	4 (12.9)	0 (0)	
<b>Choose the same pain control method for a future IUD</b>			
• Yes	15 (48.4)	20 (60.6)	0.479
• No	7 (22.6)	4 (12.1)	
• Not sure	9 (29.0)	9 (27.3)	
<b>Recommend this pain control method to a friend for IUD placement</b>			
• Yes	16 (51.6)	25 (78.1)	0.078
• No	6 (19.4)	2 (6.3)	
• Not sure	9 (29.0)	5 (15.6)	

Results are presented in raw numbers. Percent totals may not add up to 100 because of rounding.

\* p values are derived from the chi-squared test.

**Table 4:**

Results of the provider survey completed after completion of IUD placement

	<b>No Paracervical Block n = 31</b>	<b>Paracervical Block n = 33</b>	<b>p-value *</b>
Clinician type - Resident - Attending at UCSD - Nurse practitioner at PPSW	2 (6.5) 21 (67.7) 8 (25.8)	3 (9.1) 18 (54.6) 12 (36.4)	0.557
IUD type - LNG-52mg (Mirena®) - CuT380A (Paragard®) - LNG-13.5mg (Skyla®)	24 (77.4) 6 (19.4) 1 (3.2)	21 (63.6) 11 (33.3) 1 (3.0)	0.447
Purpose of IUD - Contraception - Abnormal uterine bleeding	31 (100.0) 0 (0)	33 (100.0) 0 (0)	1.000
Position of the uterus - Anteverted - Retroverted - Mid-positioned	24 (77.4) 2 (6.5) 5 (16.1)	20 (60.6) 7 (21.2) 6 (18.2)	0.205
Need for cervical dilation - No - Yes	25 (80.7) 6 (19.4)	31 (93.9) 2 (6.1)	0.108
Unable to complete IUD placement - No - Yes	31 (100.0) 0 (0)	33 (100.0) 0 (0)	1.000
Significant bleeding (>5 minutes) - No - Yes	31 (100.0) 0 (0)	32 (96.7) 1 (3.0)	0.329
Major complications - No - Yes	31 (100.0) 0 (0)	33 (100.0) 0 (0)	1.000
Ibuprofen or acetaminophen before leaving the office - No - Yes	19 (61.3) 12 (38.7)	27 (81.8) 6 (18.2)	0.068

Results are presented in raw numbers with percentages in parentheses. Percent totals may not add up to 100 because of rounding.

\* p values were derived from the chi-squared test.