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Original Article

The efficacy and safety of the ganglion impar block in chronic intractable pelvic and/or perineal pain: a systematic review and meta-analysis

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Abstract: Background: The ganglion impar is an unpaired sympathetic structure located at the level of the sacrococcygeal joint. It is controversial regarding the effect of ganglion impar block (GIB) in the treatment of chronic intractable pelvic and/or perineal pain. This meta-analysis is to provide a comprehensive assessment of the efficacy and safety concerning GIB for chronic intractable pelvic and/or perineal pain, with all the existing trials. Methods: Electronic searches were conducted in Pubmed, Embase and the Cochrane Central Register of Controlled Trials, up to May 2015. The reference lists of the relevant articles were also searched. Selecting criterion is that GIB was used in one group as a treatment of chronic intractable pelvic and/or perineal pain. The effective data were gotten from 245 patients with chronic intractable pelvic and/or perineal pain. We analyzed the overall effective rate and the visual analogue scale (VAS: 0-10) (the baseline, post-treatment and one month later) to conclude the comprehensive effect. Results: GIB can significantly improve the condition of chronic intractable pelvic and/or perineal pain, with the overall response rates (Odds Ratio (OR) = 0.01; 95% confidence interval (CI): 0.00 to 0.02; P<0.00001). There was a significant statistic difference between pre- and post-procedure of GIB (Mean Difference (MD) = -5.98; 95% CI: -7.14 to -4.81; P<0.00001). The subgroup analysis deduced the same excellent results, with pain region (pelvic area (pooled OR = 0.01; 95% CI: 0.00 to 0.05; P<0.00001) and perineal area (pooled OR = 0.01; 95% CI: 0.00 to 0.02; P<0.00001)) and method (GIB alone group (pooled OR = 0.01; 95% CI: 0.00 to 0.03; P<0.00001) and the combined group (pooled OR = 0.01; 95% CI: 0.00 to 0.03; P<0.00001)). What's more, the effect was continued to one month later (MD = -5.56; 95% CI: -6.93 to -4.18; P<0.00001). However, only few complications such as transient paresthesia and pain on injection were found. Conclusions: GIB has a evident effect on chronic intractable pelvic and/or perineal pain. This method should be used in treating chronic intractable pelvic and/or perineal pain.

Keywords: Ganglion impar block, chronic intractable pelvic pain, chronic intractable perineal pain, meta-analysis

Introduction

Chronic intractable pelvic and/or perineal pain, located in lower abdominal, pelvic or perineal area, has a high incidence, with the prevalence of 15% in humans aged 18-50 years old [1]. However, only 20-25% patients among them possess the positive reaction by the traditional conservative treatment, like drugs, local anesthesia and physical therapy etc [2, 3]. The rest intractable part, whose pain persisted for six months or more [4, 5], carried the laparoscopic diagnosis and therapy and rarely got a clear result [6], as pelvic and/or perineal pain had multiple causes and little pathological changes [6, 7].

An army of trials refer the intervention of sympathetic nervous system could be rewarding to relieve pain [8]. The ganglion impar, also called the Walther ganglion, is a part of the paravertebral sympathetic chain [9]. It is situated at the level of the sacroccygeal junction in the rear of the rectum or directly ahead of

the coccyx, responsible for the neurotransmission of the nociception and sympathetic pain of the pelvic and perineal region [10, 11]. Consequently, the ganglion impar block (GIB) may contribute to attenuate the chronic intractable pain.

However, the scope of the existing studies is so small that the results are still in dispute. And there has not been a meta-analysis to confirm the effectiveness and safety concerning this method on the management of chronic intractable pelvic and/or perineal pain. Therefore, there is an urgent need of a unified conclusion regarding GIB applied in chronic intractable pelvic and/or perineal pain. This meta-analysis was carried to comprehensively assess the efficacy and safety of GIB in chronic intractable pelvic and/or perineal pain, providing a reference basis.

Methods

The meta-analysis, estimating the efficacy and safety of GIB in chronic intractable pelvic and/or perineal pain, was undertaken according to the elaborated TREND statement [12], developed using the recommended methods.

Search strategy

Two authors (L.C.B. and F.S.P.) conducted a systematically search in Pubmed, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL). The time limitation is up to May 2015 without language restriction. The search process comprised the following key words: (chronic pelvic pain, chronic perineal pain, or chronic vulvodynia) and (ganglion impar block). The relevant references were also searched to further perfect our analysis.

Study selection and data retrieval

The included studies must meet the following criteria: (1) GIB as an intervention for chronic intractable pelvic and/or perineal pain; (2) Including the effective rate or the VAS score comparison between baseline and post-treatment. Exclusion criteria: (1) Patients with severe cardiovascular and cerebrovascular diseases or other contradictions of the block; (2) Duplications; (3) Missing data; (4) The simple qualitative description; (5) Incorrect statistical analysis performed in the report.

Data retrieval: Name of the first author, publication year, age, the types of pain, the methods of block, position, the approaches, the guiding machines, the drugs for block, number of effective cases and total patients, the VAS score of baseline, post-treatment and one month later and complications.

Qualitative assessment

The methodological quality of the included trials was assessed by two reviewers (L.C.B. and F.S.P.) independently using the TREND statement [12, 13]. Every paper was carried the thorough evaluation, from the title and abstract to discussion. There are three levels about each choice: 2-properly with detailed description, 1-mentioned but not detailed reported, 0-not mentioned or inappropriate. Trials with score ≥22 were considered as at low risk of bias, and trials with score ≤11 were considered as at high risk of bias, the left were at moderate risk of bias.

Statistical analysis

The efficacy of GIB in chronic intractable pelvic and/or perineal pain was evaluated by calculating pooled Odds Ratio (OR) and its 95% confidence intervals (CI) of the VAS score lowering less than 50%. For the continuous variable with $I^2 \geq 50\%$, we will take a random effects model. The overall effect was determined by Z test ($P<0.05$ was considered statistically significant). We undertook the sensitivity analysis to inspect existing inconformity in the current data, then we took away the high-risk papers to carry further analyze.

Subgroup analyses were carried in two different classifications, including pelvic or perineal area and GIB alone or combined with other adjunctive therapy. The VAS score in different time-point (the baseline, post-treatment and a month later) was also carried comparison. We conducted the Begg's Test and Egger's Test to assess the potential publication bias. Statistical analysis was performed with Review Manager (RevMan®) (Version 5.3; The Cochrane Collaboration, Oxford, UK) and Stata® (Version 12.0.; Stata Corp, College Station, TX, USA).

Results

Trials and patients

We totally got 73 studies by searching Pubmed, Embase, CENTRAL and the relevant references (**Figure 1**). After serious browsing the titles and abstracts, 40 irrelevant trials were removed. In the process of retrieving full-text, another 5 trials were excluded. Then we con-

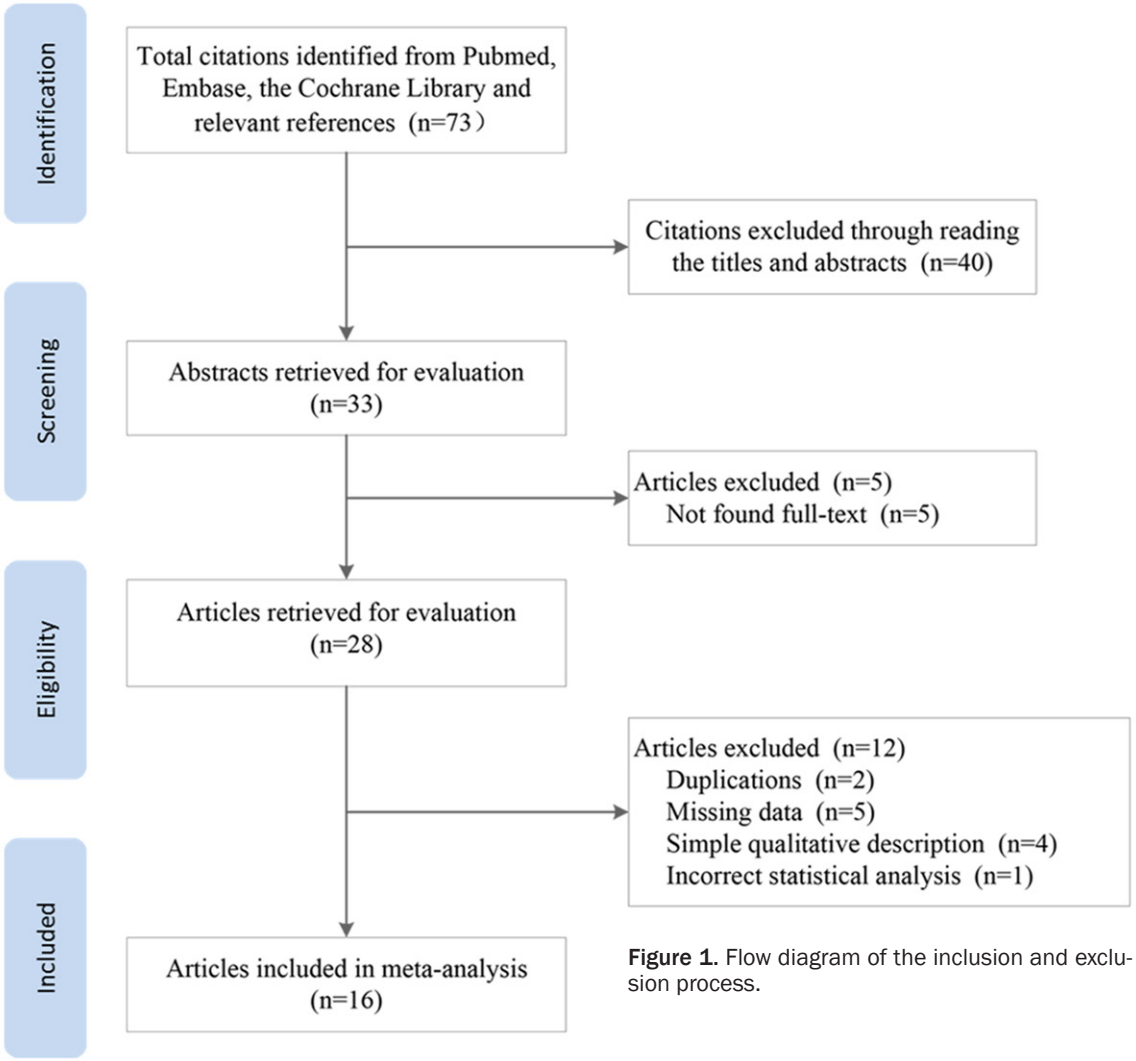

Figure 1. Flow diagram of the inclusion and exclusion process.

ducted the detailed evaluation of the papers, abandoning 12 articles due to duplications (n = 2), missing data (n = 5), simple qualitative description (n = 4), and incorrect statistical analysis (n = 1). After a series of screening, 16 trials [14-29] with 245 patients were identified in the meta-analysis.

Study characteristics and quality assessment

All the included studies [14-29] described the effective rate of GIB on chronic intractable pelvic and/or perineal pain, involving eight studies [15-17, 21, 22, 26, 28, 29] exploring the efficacy of GIB administrated alone and eight studies [14, 18-20, 23-25, 27] searching GIB combined with other treatments. Four trials [18, 19, 22, 25] reported the VAS score comparison between baseline and post-treatment. Four studies [14, 15, 18, 25] included the VAS score comparison between baseline and one month later. All studies reported few complications with the method. The characteristics of all the included studies are summarized in **Table 1**.

As the different design, the scores of the quality assessment of trails were uneven, ranging from 9 to 33, nine with low risk bias [14, 15, 18-20, 22, 24, 25, 29], five with moderate risk bias [16, 17, 26-28] and the rest five with high risk bias [21, 23] (**Table 2**).

Results of the meta-analysis

Effectiveness of GIB in pain relief: All the included studies, containing 245 patients, referred the effective rate of GIB in chronic intractable pelvic and/or perineal pain. The ratio of the rest number of patients with pain after block

Table 1. Characteristics of the included trials

Study	Year	Age	Pain	Block	Block drugs	Total	Event	VAS (0)	Complications	Follow-up
Ahmed [14]	2015	54.3±13.3	CPP# + CPP*	GIB + SHGPB	4-6 mL 8% phenol + 1 mL saline + 10 mL 10% phenol + 1 mL saline	15	5	6	5 patients transient	2 months
Malec-Milewska [15]	2014	43-73	CPP#	GIB	4-6 mL (65% alcohol + lidocaine)	9	4	4	0	3 years
Johnston [16]	2012	67	CPP*	GIB	10 mL 0.25% chirocaine + 75 ug clonidine	1	0	-	0	5 days
Sagir [17]	2011	-	CC	GIB	9 mL 0.25% chirocaine + 1 mL-40 mg methylprednisolone	1	0	-	0	-
Demircay [18]	2010	49.2±14.4	CC	GIB + RFT	10 mL 0.25% chirocaine	10	1	-	0	9.1±1.2 months
Agarwal-Kozlowski [19]	2009	64.6±12.4	CPP*	GIB + N	10 mL 1.0% ropivacaine + 2 mL 95% alcohol	43	4	7	0	4 months
Reig [20]	2005	35-76	CPP*	GIB + RFT	5 mL 0.2% ropivacaine + 40 mg triamcinolone	13	3	1	0	6 months
Park [21]	2015	-	CPP*	GIB	4 mL 0.5% lidocaine + 5 mL 0.2% ropivacaine + 20 mg triamcinolone	4	0	1	0	3 months-2 years
Gunduz [22]	2015	41±9	CC	GIB	2 mL 0.5% bupivacaine + 2 mL saline + 40 mg methylprednisolone	22	4	2	0	6 months
Mastroluca [23]	2011	-	CPP*	GIB + PR	-	11	3	-	0	6 months
Abejon [25]	2007	53±17	CPP*	GIB + RFT	-	35	21	3	0	1 year
Plancarte-Sanchez [26]	2005	24-87	CPP*	GIB	4 mL (1% lidocaine or 0.25% bupivacaine) + 4-6 mL 10% phenol	16	0	8	0	14-120 days
Hamaguchi [27]	2003	62	CPP*	GIB + CB	5 mL 0.25% bupivacaine + 4 mL 7% phenol	1	0	1	0	6 months
Swofford JB [28]	1998	35-70	CPP*	GIB	5 mL 0.25% bupivacaine + 20 mg triamcinolone	20	0	7	0	-
Anwer [24]	2011	-	CPP# + CPP*	GIB + N	Bupivacaine + absolute alcohol	14	0	5	0	1 month
Ozyalcin [29]	1996	36-68	CPP*	GIB	6 mL 0.25% bupivacaine + 6 mL 6% phenol	30	6	-	0	6 months

CPP# = Chronic pelvic pain; CPP* = Chronic perineal pain; GIB = The ganglion impar block; SHGPB = The superior hypogastric plexus block; CC = Chronic coccydynia; RFT = Radiofrequency thermocoagulation; PR = Pulsed radiofrequency; CB = Caudal block; N = Neuroablation.

Table 2. The TREND score of included studies

Study	Standard TREND checklist items																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	SUM
Ahmed [14]	2	2	1	1	1	2	0	0	0	1	1	2	2	1	1	1	1	1	2	1	2	2	27
Malec-Milewska [15]	1	2	1	0	2	2	1	0	0	1	1	2	2	2	1	0	0	1	2	1	2	1	25
Johnston [16]	1	2	0	0	2	1	0	0	0	0	0	0	1	1	0	0	0	1	1	1	1	1	13
Sagir [17]	1	2	1	1	2	1	0	0	0	1	0	0	0	0	0	1	1	0	2	1	2	0	16
Demircay [18]	2	2	1	2	2	1	1	0	0	2	2	2	1	2	2	1	1	1	2	2	2	1	32
Agarwal-Kozlowski [19]	2	2	1	1	2	2	1	0	0	1	2	2	2	2	2	1	1	1	2	2	2	2	33
Reig [20]	1	2	1	0	2	2	1	0	0	0	0	2	1	2	1	0	1	0	2	1	2	2	23
Park [21]	1	1	0	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	1	1	1	0	9
Gunduz [22]	2	2	1	1	2	2	0	0	0	1	2	0	1	2	1	1	1	0	2	1	2	1	25
Mastroluca [23]	1	1	0	0	1	1	0	0	0	0	0	0	1	0	0	0	0	0	2	1	1	1	10
Abejon [25]	2	2	1	1	2	2	0	0	0	1	2	2	2	1	1	0	1	0	2	2	2	1	27
Plancarte-Sanchez [26]	1	2	1	0	2	1	0	0	0	0	0	2	2	1	1	0	1	1	2	1	2	1	21
Hamaguchi [27]	1	1	0	0	2	1	1	0	0	0	0	2	2	0	0	0	1	0	2	2	2	2	19
Swofford JB [28]	1	1	0	0	2	1	0	0	0	0	1	0	0	1	1	1	0	0	2	1	2	1	15
Anwer [24]	2	2	1	0	2	1	0	0	0	1	2	1	0	1	1	0	1	0	2	2	2	1	22
Ozyalcin [29]	2	1	0	1	2	1	0	0	0	2	2	1	0	1	1	1	0	0	2	2	2	1	22

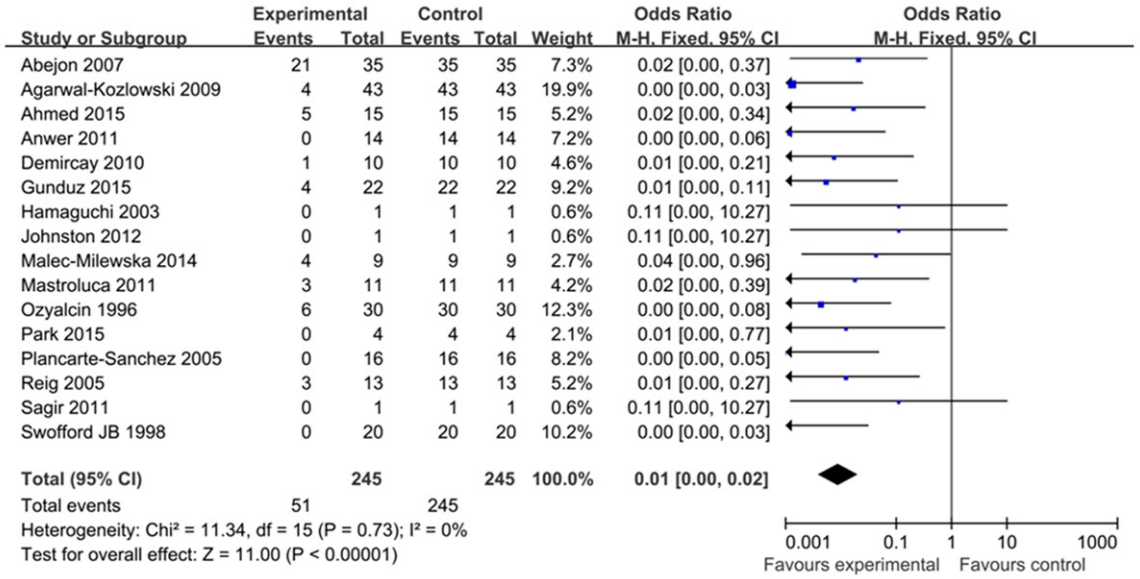

Figure 2. The ratio of the rest number of patients with pain after GIB.

was significant decreased (pooled OR = 0.01; 95% CI: 0.00 to 0.02; *P*<0.00001) (**Figure 2**). In the subgroup analysis of pain region, GIB significantly relieved the chronic pelvic pain (pooled OR = 0.01; 95% CI: 0.00 to 0.05; P< 0.00001) and perineal pain (pooled OR = 0.01; 95% CI: 0.00 to 0.02; P<0.00001) (**Figure 3**). The number of patients with pain was also reduced in GIB alone group (pooled OR = 0.01; 95% CI: 0.00 to 0.03; P<0.00001) and the combined group (pooled OR = 0.01; 95% CI: 0.00 to 0.03; P<0.00001) (**Figure 4**). About the effective rate, there is no significant publication bias in Begg's test (*P* = 0.177) and Egger's test (*P* = 0.571).

The changes of the VAS scores

The VAS score, indicators of pain, was measured in all the included papers. Four trials [18,

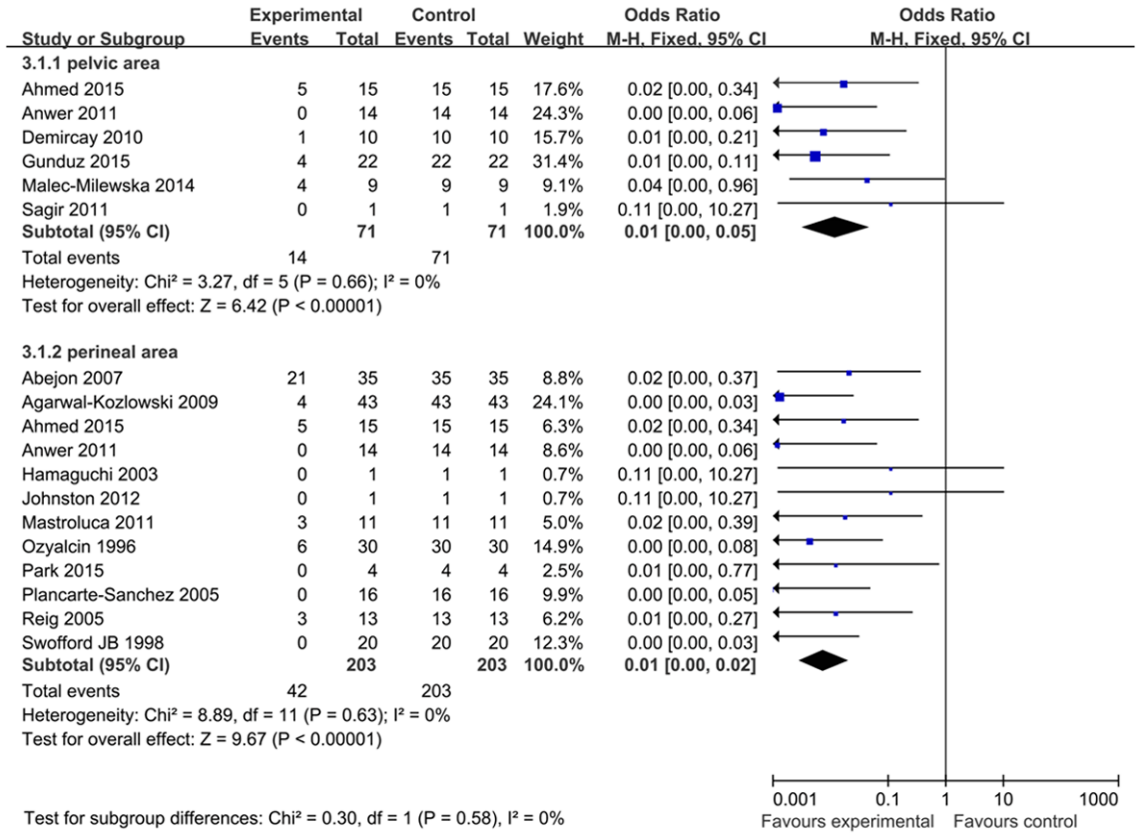

Figure 3. Results of subgroup analysis of the ratio of the rest number of patients with pain after GIB by area.

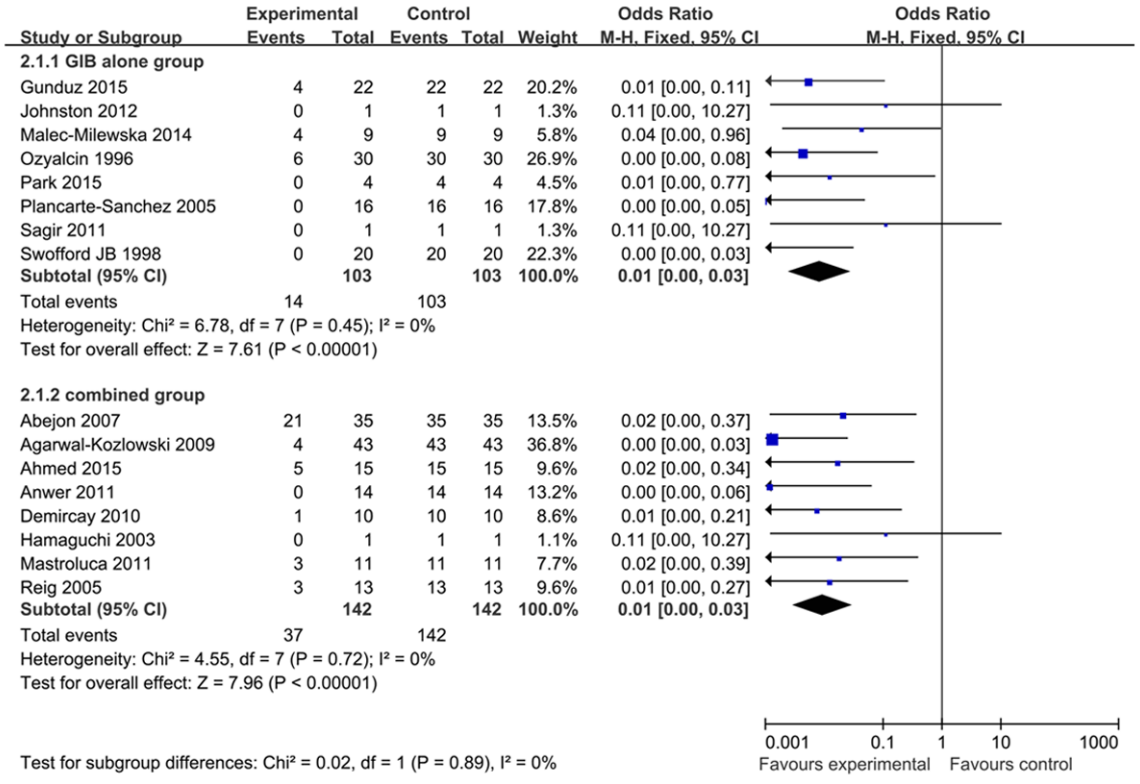

Figure 4. Results of subgroup analysis of the ratio of the rest number of patients with pain after GIB by block method.

Table 3. The VAS score in the baseline and post-procedure

Study	Year	The VAS score		Number of patients	MD (95% CI)
		Baseline	Post-procedure		
Abejon [25]	2007	8.1±1.6	4.2±3.2	35	-3.90 [-5.09, -2.71]
Agarwal-Kozlowski [19]	2009	8.2±1.6	2.2±1.6	43	-6.00 [-6.68, -5.32]
Demircay [18]	2010	8.70±0.67	1.60±0.51	10	-7.10 [-7.62, -6.58]
Gunduz [22]	2015	8.77±1.15	2.16±2.29	22	-6.61 [-7.68, -5.54]
Total				110	-5.98 [-7.14, -4.81]

Table 4. The VAS score in the baseline and one month later

Study	Year	The VAS score		Number of patients	MD (95% CI)
		Baseline	1 month		
Abejon [25]	2007	8.1±1.6	4.1±2.8	35	-4.00 [-5.07, -2.93]
Ahmed [14]	2015	7.87±1.19	2.87±2.62	15	-5.00 [-6.46, -3.54]
Demircay [18]	2010	8.70±0.67	2.10±0.87	10	-6.60 [-7.28, -5.92]
Malec-Milewska [15]	2014	8.33±1.41	1.76±1.71	9	-6.57 [-8.02, -5.12]
Total				69	-5.56 [-6.93, -4.18]

19, 22, 25] recorded the score in the baseline and post-procedure (**Table 3**). After the operation, an obvious declining of the score were gotten (MD = -5.98; 95% CI: -7.14 to -4.81; $P<0.00001$), indicating a perfect pain relief. Four trials [14, 15, 18, 25] provided the score in the baseline and one month later (**Table 4**). There was a significant difference of the VAS score (MD = -5.56; 95% CI: -6.93 to -4.18; $P<0.00001$).

Complications

All the included studies described the complications of GIB. Of all the 245 participants, however, there were only five patients with transient paresthesia and three patients with injection pain [14].

Discussion

Chronic intractable pelvic and/or perineal pain is still a serious challenge for modern medicine and can induce various severe complications, such as substantial functional impairment, depression and even desperation. Currently, there is an emergent need to find an effective treatment for this.

The present meta-analysis was undertaken to evaluate the efficacy and safety of GIB in chronic intractable pelvic and/or perineal pain. The main findings are as follows: (1) Comparing the pretherapy and post-treatment, GIB could obviously relieve the chronic intractable pain, either pelvic or perineal pain, and the effect was sustained until one month later. (2) For the chronic intractable pelvic and/or perineal pain, GIB alone could significantly improve the condition of pain. Combining GIB with other technologies, a better curative effect could be gotten.

The ganglion impar, a single structure usually found at the anterior aspect of the sacrococcygeal joint, is the lowest ganglion of the paravertebral sympathetic chain [9, 30, 31]. The autonomic sympathetic nervous system takes a role, conveying nociceptive messages from the viscera to the brain [32]. Cutting off the information transmission channel, so GIB can improve the condition of chronic intractable pelvic and/or perineal pain [33].

Nowadays, this method hasn't been widely accepted, just because it is an invasive operation. However, the current technology, guided with C-arm fluoroscopy and through the transsacro-coccygeal approach, can decrease the occurrence of complication significantly. In all the 245 patients, we only found five patients with transient paresthesia and three patients with pain on injection.

For all we know, this is the first try to analyze the efficacy and safety of GIB in chronic intractable pelvic and/or perineal pain with a comprehensive quantitative method. It's worth noting that detailed and comprehensive retrieval were carried in our meta-analysis, solving the limitation of original studies with small scales. Moreover, concerning time to curative effect, we not only focused on post-procedure, but also the condition of pain was carried comparison one month later. In the process of analyses, the overall effect and various factors have been operated in different models. To be sure, the result of our meta-analysis is authentic and creative. However, some limitations still existed. First, as GIB is an invasive procedure, the included trails are not the randomized controlled trials. Second, the articles were designed as short-term studies without evaluating the long-term effects of GIB, like a year or five years after treatment.

In conclusion, this meta-analysis demonstrated that GIB can effectively alleviate the chronic intractable pain with few complications. And our results provided the true and reliable evidence for the clinical application of GIB in chronic intractable pelvic and/or perineal pain. Accordingly, the clinicians should further understand this method and keep improving it. Nevertheless, we don't primarily recommend GIB for the general pain because of the probable damage of nerve. Further investigations should be operated to explore and improve the application of GIB.

Disclosure of conflict of interest

None.

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