Compression therapy after posterior lumbar decompression and internal fixation: a prospective, randomized, clinical study

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Abstract

Background: Wound-related complications have become an inevitable problem for spinal surgeons. Negative pressure drainage is the main method to prevent postoperative hematoma and related complications, which is still controversial. This prospective, randomized, controlled study was designed to evaluate the efficacy of compression therapy in the treatment of complications after posterior decompression and internal fixation of the lumbar spine, with emphasis on pain, anemia and inflammation. Methods: Sixty consecutive patients with an average age of 59 years (43–78 years) who were selected for posterior lumbar decompression and internal fixation were randomly assigned into two groups with an equal number of patients. The groups comprised patients on closed suction drain with compression therapy after surgery or those with closed suction drain alone. The drainage volume, visual analogue scale pain score for back pain, white blood cell and red blood cell counts, hemoglobin levels, erythrocyte sedimentation rate, and C-reactive protein levels on the 1st, 3rd, and 10th days after the operation were compared between the two groups. Results: The average follow-up was 6 months and ranged from 3 to 11 months. Drainage volume, the visual analogue scale score, and C-reactive protein levels on the 10th day after the operation were significantly lower in the treatment group than in the control group. The red blood cell count and hemoglobin levels on the 3rd and 10th days after the operation were significantly higher in the treatment group than in the control group (all $P<0.05$). At the time of discharge, wounds in the two groups showed grade A healing, and there were no signs of late infection in the groups. Conclusions: For postoperative posterior lumbar decompression and internal fixation, compression therapy relieves pain, alleviates anemia and the inflammatory response.

Background

As the older population continues to increase worldwide, degenerative lumber disease has also increased[1,2]. For patients who fail conservative treatment, posterior decompression is the most common treatment[3,4]. However, because of the requirement of visual field exposure, the paravertebral muscle should be separated on a large scale and stretched for a long time during the posterior operation. Soft tissue edema and hematoma in the operative field can increase tension on incisions, cause pain and fever, even lead to wound infection [5,6]. Moreover, epidural hematoma can lead to spinal cord compression and even paralysis[7]. For patients with internal fixation, these complications not only impair clinical outcomes and the patient's satisfaction, but also notably increase the risk for implant infection[8].

Currently, negative pressure drainage is the main method of preventing postoperative hematoma and related complications[9,10]. Negative pressure drainage can accelerate wound healing by advancing angiogenesis, increasing microvascular blood flow, stimulating granulation tissue formation, and reducing edema[11]. Therefore, use of negative pressure drainage in posterior spinal surgery remains controversial. A few studies have showed that negative pressure drainage has no benefit in spinal surgery [12,13]. In contrast, closed suction drainage could increase postoperative blood loss, and the need for transfusion[14].

Compression therapy reduces pain and blood flow, development of edema, swelling, and hemarthrosis, protects soft tissues [15], increases range of motion, and improves function[16]. Therefore, this therapy is widely used in preventing deep venous thrombosis[17], edema management, ankle fracture[18], shoulder/knee arthroscopy, and wound care [15-17]. However, there have been no reports on the use of compression therapy after posterior lumbar decompression and internal fixation.

Therefore, this prospective, randomized, clinical study aimed to investigate the effect of compression therapy on the postoperative course of posterior lumbar decompression and internal fixation, with special focus on pain, anemia, and inflammatory reactions.

Methods

In the description of our study design, we follow the Consolidated Standards of Reporting Trials (CONSORT statement).

This was a randomized unblinded prospective study, which was reviewed and approved by the Medical Ethics Committee of Wangjing Hospital of the China Academy of Chinese Medical Sciences(WJEC-KT-2017-013-P002), and was preregistered in the Chinese Clinical Trial Registry (ChiCTR1800015825). Confidentiality was maintained with all patient records.

Currently, the negative pressure drainage is controversial and there is no literature report of compression therapy on the postoperative course of posterior lumbar decompression and internal fixation. Therefore, we proposed to recruit 60 patients to investigate the effect of compression therapy on the postoperative course of posterior lumbar decompression and internal fixation, these patients will randomly assigned into two groups with an equal number.

From May 2018 to January 2019, a total of 76 patients with lumbar spinal stenosis with documented evidence of symptomatic lumber spinal stenosis confirmed by clinical, computed tomography, and magnetic resonance imaging (MRI) findings were performed posterior lumbar decompression and internal fixation by the first author. Among them, 60 patients were recruited into the study，all these patients provided written informed consent for the public use of their treatment data and related pictures. Inclusion and exclusion criteria are listed in Table 1.

Patients younger than 40 years or with other risk factors[8,19,20] were excluded. Only patients aged older than 40 years, with typical clinical symptoms of lumbar spinal stenosis, and radiological confirmation were included in the study.

Patients were assigned to the treatment group (closed suction drain(CSD) with compression therapy) or to the control group (CSD alone) by a random number generator before the trial started. The same standard surgical technique was performed on all patients.

In the treatment group (CSD with compression therapy), a 16 Fr silicone CSD (Fr-16; Shandong Branden Medical Devices Co., Ltd., Shandong City, China) was inserted into the surgical area. All CSDs were used

with mild suction pressure (half negative). For compression therapy after the operation, a sterile gauze bandage was used and the aseptic dressing was folded into a shuttle shape (Fig. 1), which was preferably thick to counteract the lumbar lordosis. At the same time, an elastic waist band (PCS-5011; Rehan Health Care Co., Ltd., Shanghai City, China) was applied for pressure. Before operation, we laid the cuff of the cuff sphygmomanometer in the middle of the patients' waist in prone position, tightened the inflatable valve when the mercury column was about to rise, pressed it with elastic waist band, and marked it when the pressure reached 20 mmHg and 40 mmHg[21], respectively(Fig. 2,3). The elastic waist band was worn as far as possible to the 40 mmHg marking lines after the operation, if the patients complain problems with breathing or abdominal discomfort, the elastic waist band was loosed according to the patient's preference, but cannot exceed the 20mmHg marking line (Fig. 4). If relaxing the elastic waist band to 20mmHg still does not relieve the symptoms, remove the elastic waist band and this patient drop out of the study. The elastic waist band was worn until the wound healed after the operation. In the control group, CSD alone was administered in the same manner as described for the treatment group.

The patients' back pain was assessed with the visual analogue scale (VAS). The most painful back wound VAS score after the operation was recorded. The patients' drainage volume (postoperatively, the CSD was removed when the amount of bleeding did not exceed 100 mL per day, and the total drainage volume was recorded), white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin (Hb) levels, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) levels [22] on the 1st, 3rd, and 10th days after the operation were recorded. These indicators were compared between the two groups to evaluate the effects of compression therapy for postoperative posterior lumbar decompression and internal fixation. All of the 60 patients were available for follow-up, and postoperative complications were recorded at follow-up. The mean duration of follow-up was 6.25±2.36 months.

Statistical analysis was performed using SPSS 22.0 software (IBM Corp., Armonk, NY, USA). Measurement data are presented as the mean (standard deviation). The Kolmogorov–Smirnov test and histograms indicated a non-parametric distribution of the data. Significance of differences of outcome measures between the two groups was analyzed using the independent sample test or Mann–Whitney U test ($p<0.05$) depending on normal distribution. Numeration data between the two groups were compared using the chi-square test.

Results

A CONSORT flowchart is presented in Fig. 5 to demonstrate the recruitment, allocation and flow of the trial. The number of patients who were managed with CSD and compression therapy or CSD alone was 30 in each group. Table 2 shows comparison of patients' demographics and known risk factors for wound healing between the treatment and control groups before the intervention. There were no significant differences in these data between the treatment and control groups.

In the treatment group, five patient complain breathing problems and nine patients with abdominal discomfort when the elastic waist band was worn near the 40 mmHg marking lines, after loosed the elastic

waist band to the 20mmHg marking line, the symptoms were gone, and not one patient dropped out of the study. Drainage volume, the VAS score, and CRP levels on the 10th day after the operation were significantly lower in the treatment group than in the control group (all $p<0.05$). The RBC count and Hb levels on the 3rd and 10th days after the operation were significantly higher in the treatment group than in the control group (all $p<0.05$, Table 3). At the time of discharge, the wounds of the two groups showed grade A healing, and there were no signs of late infection or complications in either group at follow-up.

The postoperative drainage volume, the VAS score in the treatment group were significantly lower than those in the control group. These findings suggested that compression therapy reduced drainage, and relieved pain.

The RBC count and Hb levels on the 3rd and 10th days after the operation were significantly higher in the treatment group than in the control group. However, CRP levels on the 10th day after the operation were significantly lower in the treatment group than in the control group (Fig. 6–8). These findings suggested that compression therapy alleviated anemia and the inflammatory response.

Discussion

The posterior approach is the most commonly used surgical approach for lumbar spinal surgery because of its advantages of a safe operation and clear exposure. However, the incidence of wound-related complications after spinal surgery fluctuates from 0.4% to 20%[23-25]. This has become an unavoidable problem for spinal surgeons. Negative pressure drainage has been the main method of preventing postoperative hematoma and related complications[9-11]. Therefore, use of negative pressure drainage in posterior spinal surgery remains controversial[12-14].

Compression therapy is widely used for treating complex wound healing and scar hyperplasia [15-18], but there have been no reports on the use of compression therapy after posterior lumbar surgery. In clinical work, use of an elastic waist band after the operation can relieve pain of the waist wound when turning over. To evaluate the effect of compression therapy on posterior lumbar decompression and internal fixation, we selected 60 patients for a prospective, randomized, clinical trial. To improve comparability, factors that may affect the incidence of wound complications after lumbar surgery, such as chronic steroid use and diabetes were excluded[8,19,20]. To offset lumbar lordosis, the aseptic dressing was folded into a shuttle shape. We found that after posterior lumbar internal fixation, compression therapy has the effects of relieving fever anemia and the inflammatory response.

The mechanisms of how compression therapy causes these effects could be as follows. (1) Mechanical stress produced by the elastic waist band causes paravertebral muscles of the incision to move toward the center, these changes could reduce the dead space and decrease the incidence of hematomas in the operative cavity[26]. (2) The aseptic dressing was folded into a shuttle shape to offset lumbar lordosis. This could lead to a decrease in negative pressure in the operative cavity, further reducing exudation and the release of inflammatory mediators. (3) Mechanical stress can decrease partial pressure of oxygen in the

wound tissue, stimulate the start signal of repair, this situation is conducive to timely removal of necrotic tissue and a reduction in release of inflammatory mediators in the wound[26]. (4) Mechanical stress controls collagen synthesis by limiting the supply of blood and oxygen, reduces collagen production, and encourages realignment of collagen bundles that are already present to accelerate wound healing[27].

One of the concerns about the routine use of an elastic waist band is the added cost for the procedure. The equipment cost is only $20 per patient. No additional cost is required by application of the elastic waist band, and coordination of dressing changes with a special nurse or wound specialist is not required. Therefore, compression therapy is available for primary medical organizations.

There are some limitations of our study as follows. (1) If elasticity of the elastic band decreases during the process, maintaining a fixed pressure in the back wound is difficult. (2) There was no postoperative MRI examination to better understand hematomas in the operative area. (3) The study findings were limited by the small sample size and the single-center design. A multicenter, randomized, controlled study is required to further confirm these results.

Conclusion

This study is the first to demonstrate the effect of compression therapy for treating postoperative posterior lumbar decompression and internal fixation. Because of the curative effect, low cost, simple operation, and high compliance of patients, we believe that using compression therapy on postoperative posterior lumbar decompression and internal fixation should be considered.

Abbreviations

MRI, magnetic resonance imaging; CSD, closed suction drain; VAS, visual analogue scale; WBC, white blood cell; RBC□red blood cell□Hb□hemoglobin□ESR□erythrocyte sedimentation rate□CRP□C-reactive protein □

Declarations

Ethics approval and consent to participate

The study was reviewed by the Medical Ethics Committee of Wangjing Hospital of the China Academy of Chinese Medical Sciences with the number: WJEC-KT-2017-013-P002.Participants provided consent with an approved informed consent document before enrollment in the study, all patients provided written informed consent for the public use of their treatment data and related pictures.

Consent for publication

Not applicable.

Availability of data and material

The data sets analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LGZ and JHG were involved in obtaining the grant, designing the study and generated the random allocation sequence. WS and BJW were involved in enrolled participants, assigned participants to interventions, data collection and analysis. WX and ZZW were involved in writing and implementing the protocols. KXY and Q supervised all phases of this research project. All authors participated throughout the writing process and have read and approved the final version.

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Tables

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age greater than 40 years[19]	Under 40 years of age
Low back pain/intermittent claudication [8]	Decompression without internal fixation
CT/MRI confirmed lumbar spinal stenosis	Back or leg pain of unknown aetiology
Failed conservative treatment for 2 weeks	Systemic or local infections
Posterior lumbar decompression and disease internal fixation in Department of Spine 2.	Chronic steroid use, Diabetes, hemato-oncological disease, renal disease, autoimmune [20]
Blood Transfusion in perioperative period	

Table 2. Comparison of general data and laboratory indices between the treatment and control groups before the intervention

	Treatment group (n = 30)		Control group (n = 30)					
	n	Mean(SD)	n	Mean(SD)	χ^2-value	z-value	t-value	p-value
Age		57.77(9.02)		60.43(9.06)	-	-	-1.14	0.26
Gender					0.07	-	-	0.79
Male	12		11					
Female	18		19					
BMI		26.11(3.61)		26.51(3.06)	-	-	-0.46	0.64
Surgical segment (number)		2.40(0.56)		3.00(0.52)	-	-3.89	-	0.09
Surgery duration (min)		175.67(42.48)		180.67(30.05)	-	-	-0.53	0.60
Blood loss (mL)		282.33(92.87)		337.33(131.20)	-	-1.58	-	0.11
Laboratory indexes								
WBC (10^9/L)		5.97(1.55)		5.91(1.42)	-	-	0.16	0.87
RBC (10^9/L)		4.63(0.46)		4.54(0.49)	-	-	0.73	0.47
Hb (g/L)		140.33(15.40)		140.30(14.42)	-	-	0.01	0.99

Table 3. Comparison of general data and laboratory indices between the treatment and control groups after the intervention

	Treatment group (n = 30)	Control group (n = 30)			
	Mean(SD)	Mean(SD)	z-value	t-value	p-value
Drainage volume (mL)	332.33(131.98)	447.00(178.46)	-	-2.83	0.006*
Maximum VAS (cm)	3.07(1.20)	4.00(1.13)	-3.26	-	0.001*
WBC[1] (10^9/L)	12.78(3.21)	12.60(2.99)	-	0.223	0.825
RBC[1] (10^9/L)	4.02(0.70)	3.76(0.49)	-	1.656	0.103
Hb[1] (g/L)	119.10 (15.17)	116.10 (14.38)	-	0.786	0.435
ESR[1] (mm/h)	13.97(8.59)	12.80(10.67)	-	0.466	0.643
CRP[1] (mg/L)	24.20(16.81)	32.35(18.77)	-	-1.771	0.082
WBC[3] (10^9/L)	10.83(2.76)	10.20(2.27)	-	0.964	0.339
RBC[3] (10^9/L)	3.84(0.50)	3.46(0.53)	-	2.896	0.005*
Hb[3] (g/L)	116.77(13.54)	107.10 (15.99)	-	2.527	0.014*
ESR[3] (mm/h)	32.30(22.65)	34.73(26.96)	-	-0.378	0.706
CRP[3] (mg/L)	44.06(48.64)	60.23(51.43)	-	-1.251	0.216
WBC[10] (10^9/L)	8.48(1.77)	7.57(2.38)	-	1.676	0.099
RBC[10] (10^9/L)	5.68(2.27)	4.66(1.54)	-	2.040	0.047*
Hb[10] (g/L)	120.37 (14.77)	109.53(22.26)	-	2.221	0.030*
ESR[10] (mm/h)	34.90(20.01)	34.59(22.31)	-	0.056	0.955
CRP[10] (10^9/L)	13.87(11.24)	23.14(19.30)	-	-2.273	0.028*

[1]First day after the operation; [3]3rd day after the operation; [10]10th day after the operation.

*Statistical difference ($p<0.05$).

Figures

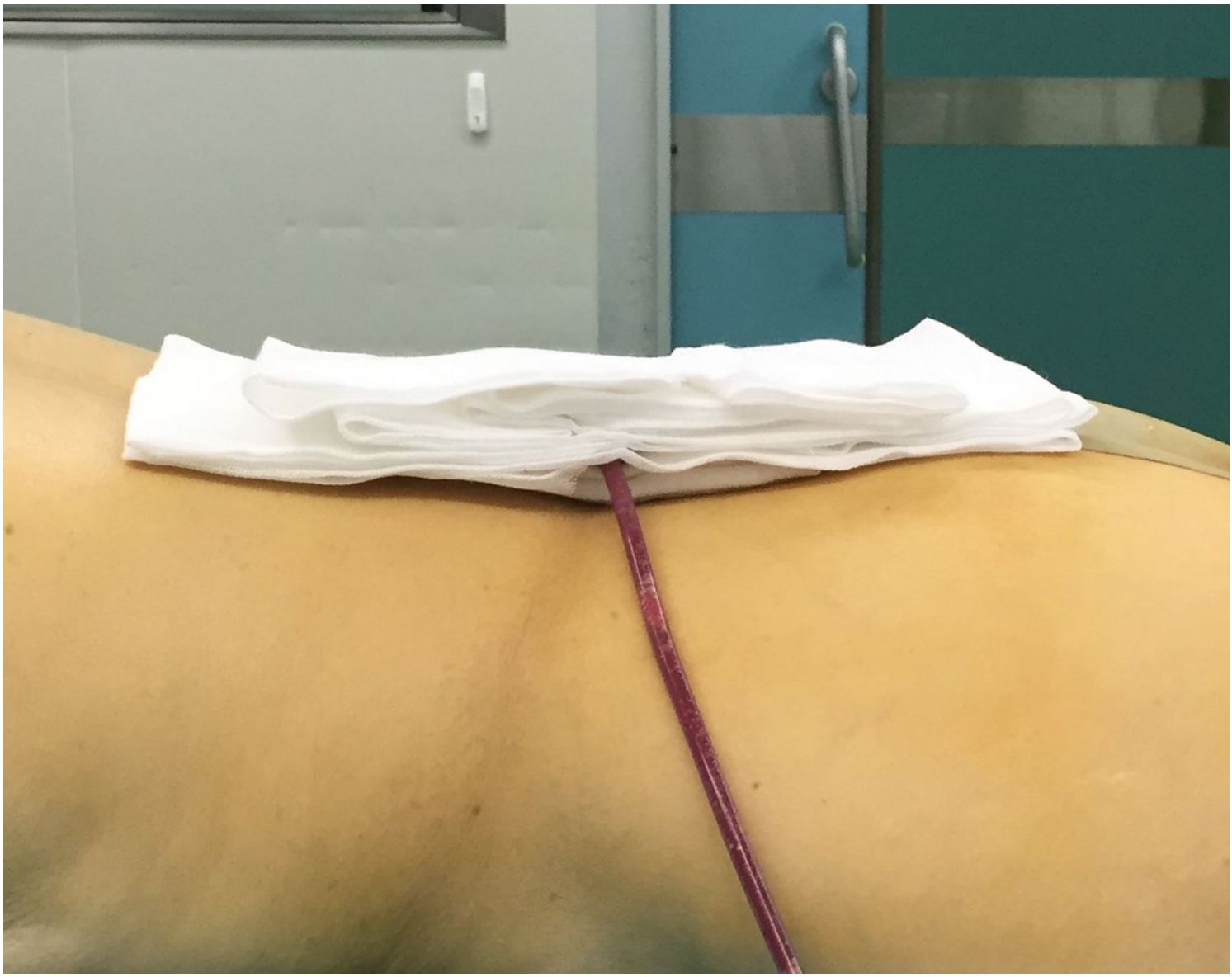

Figure 1

The dressing was folded into a shuttle shape to counteract the lumbar lordosis

Figure 2

The cuff sphygmomanometer used to marking lines at 20 and 40 mmHg

Figure 3

The cuff sphygmomanometer used to marking lines at 20 and 40 mmHg

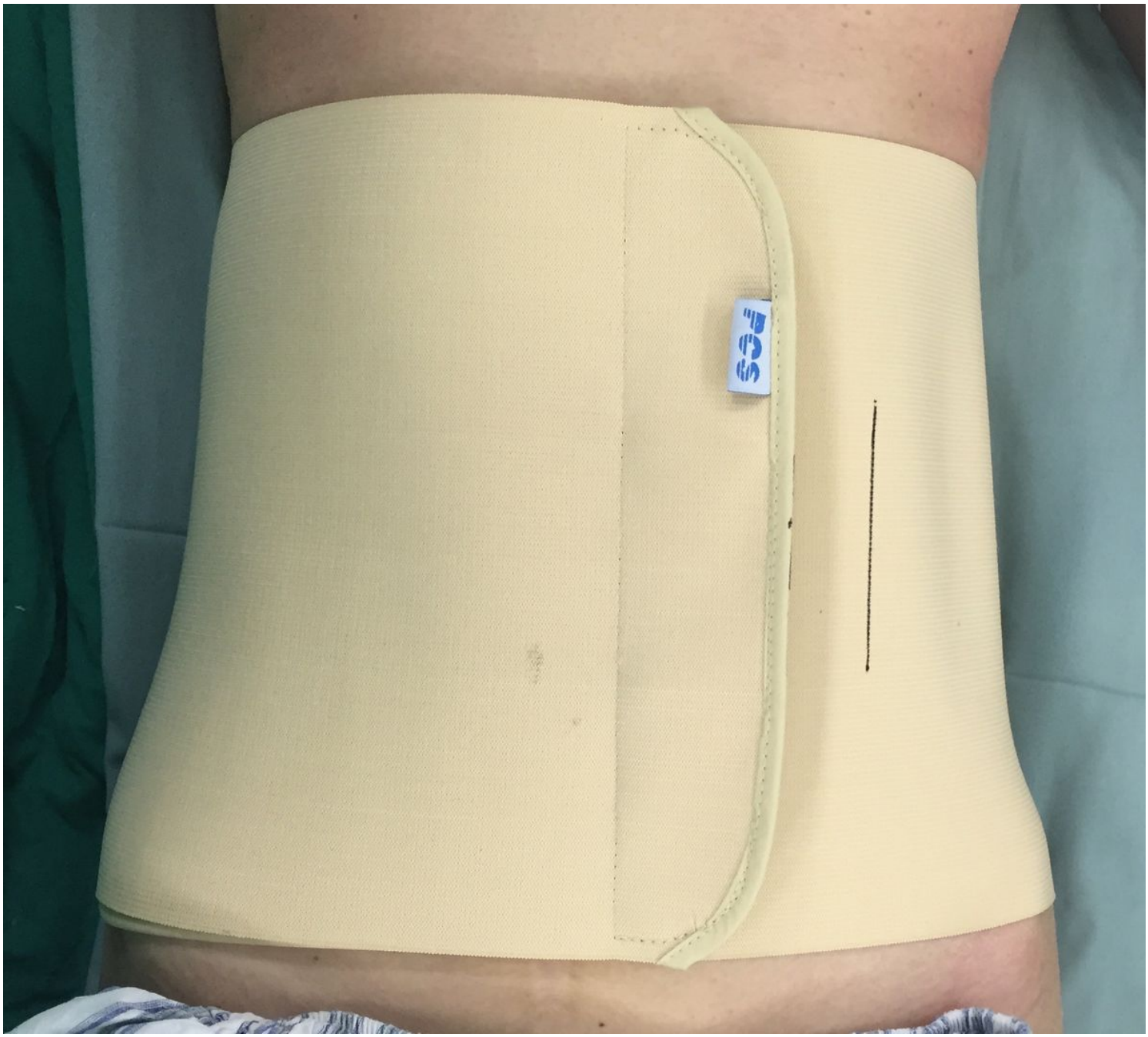

Figure 4

The elastic waist band was worn between the two marking lines.

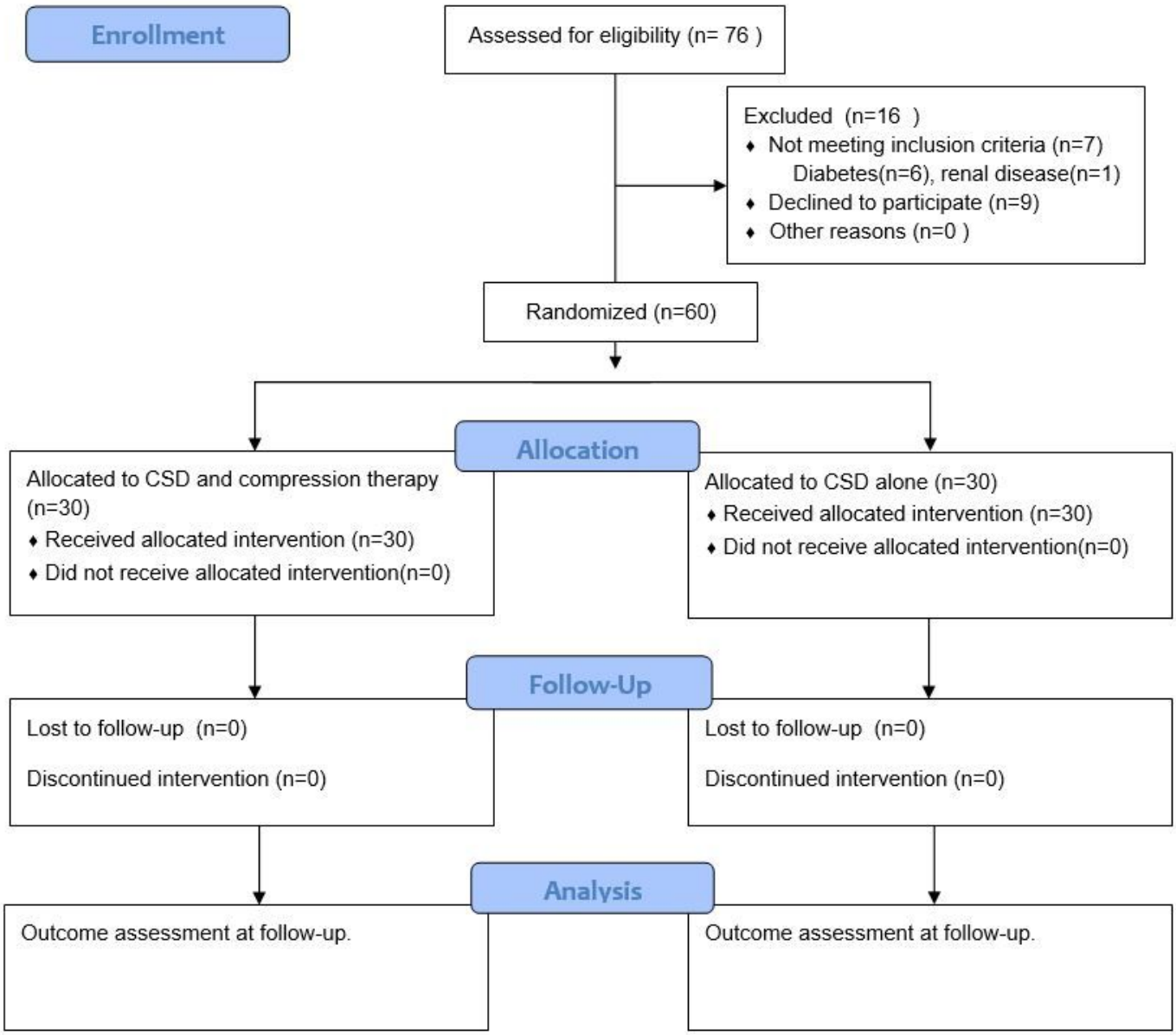

Figure 5

CONSORT flowchart - the recruitment process of participants into the trial

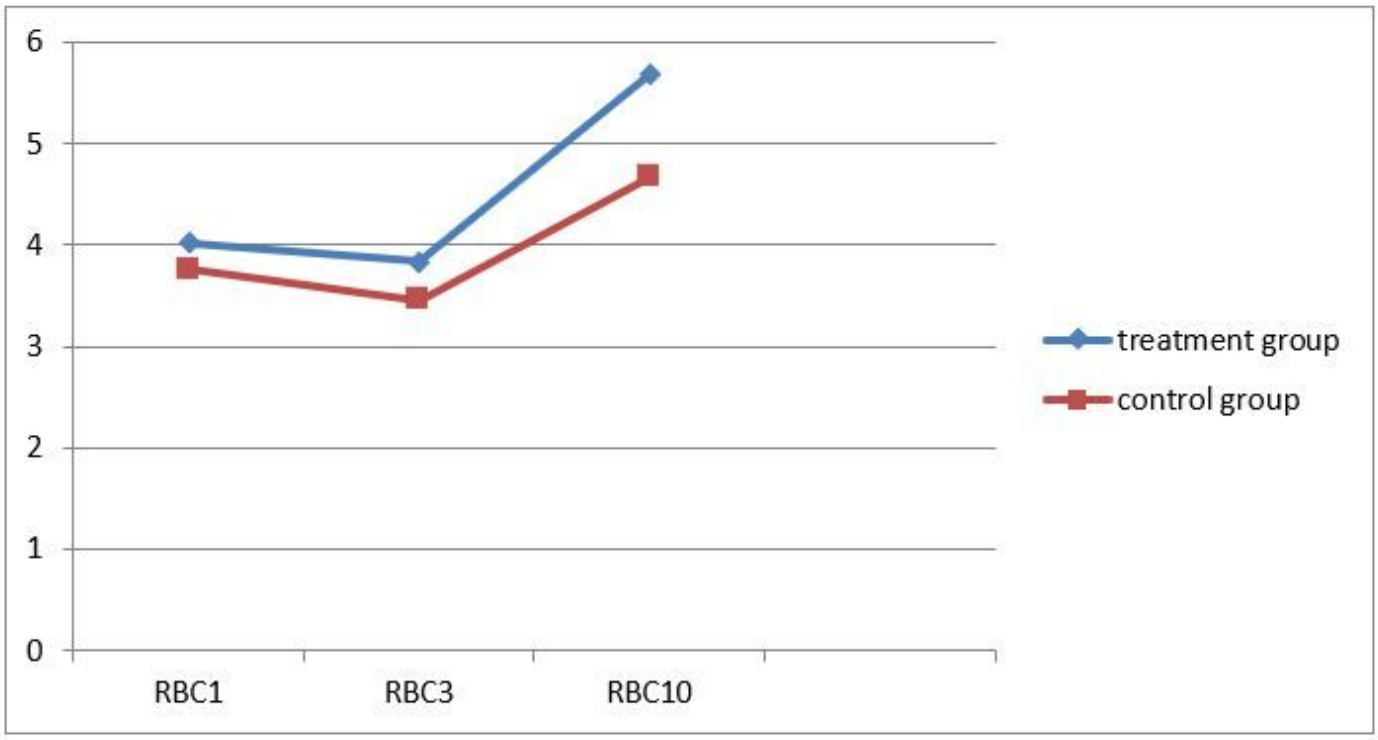

Figure 6

Changes in the RBC count (10^9/L) between the two groups.

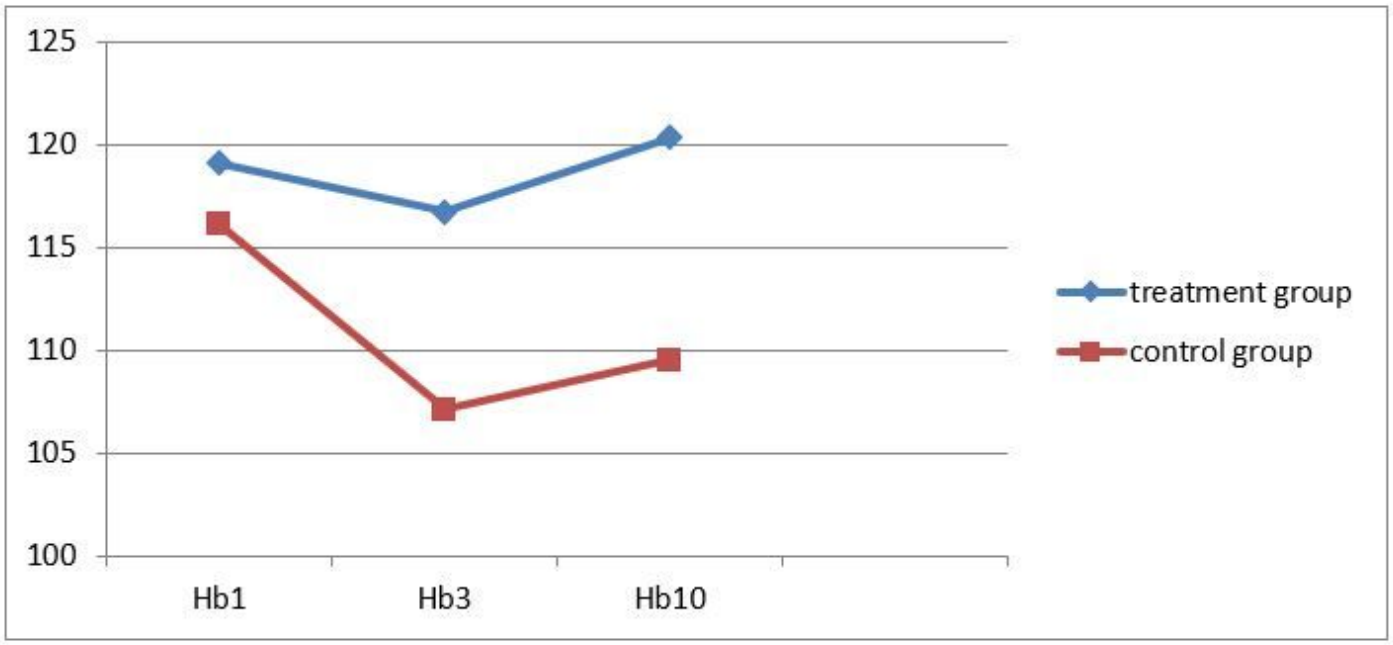

Figure 7

Changes in Hb levels (g/L) between the two groups.

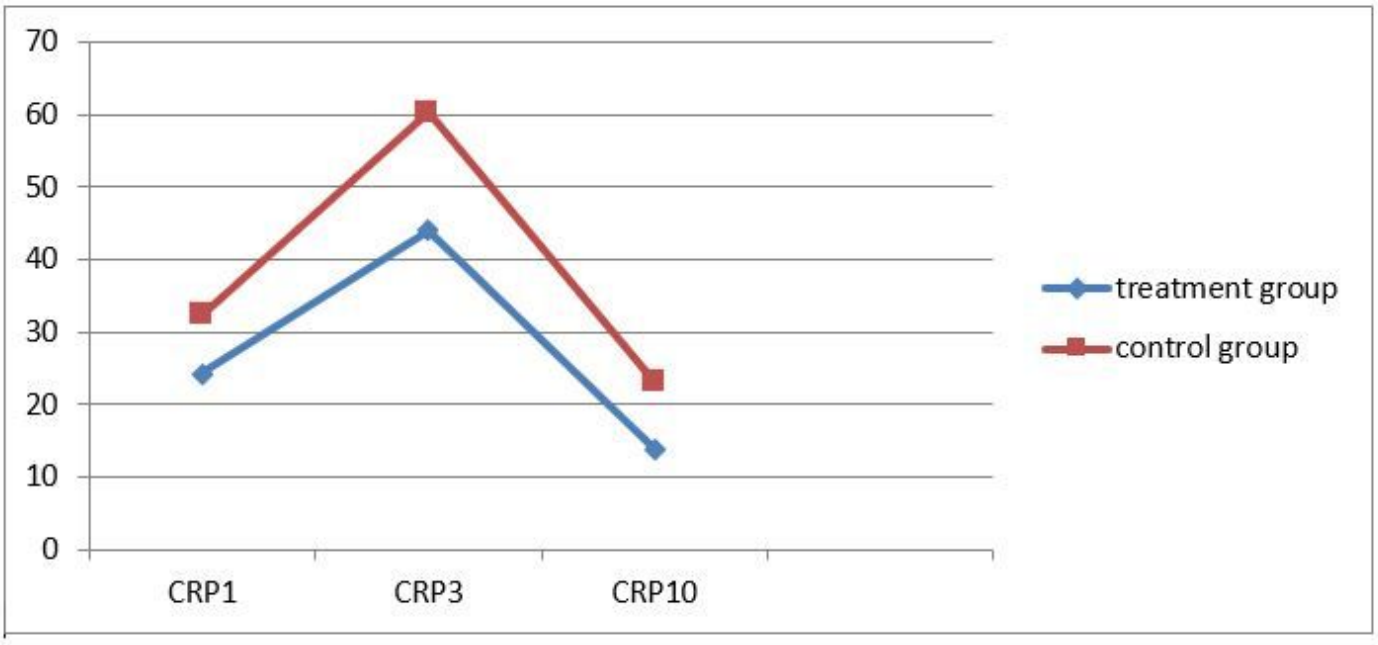

Figure 8

changes in CRP levels (mg/L) between the two groups.

Supplementary Files

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