



Original contribution

Blood-sparing efficiency of transdermal nitroglycerine during open fixation of femur shaft fractures: a randomized, double-blind study[☆]

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Abstract

Study Objectives: To evaluate the effect of transdermal nitroglycerine for reducing blood loss during open fixation of femur shaft fractures.

Design: Randomized, double blind, clinical trial.

Setting: University-affiliated hospital.

Patients: 60 ASA physical status I and II patients undergoing elective open fixation of femur shaft fractures.

Interventions: Patients were randomized to two groups: those who received 3-in (7.5 cm) transdermal nitroglycerine (group N) or 3-in (7.5 cm) placebo (group P). All the drugs used for induction and maintenance of anesthesia were similar in both groups and administered according to the patient's weight.

Measurements: In both groups, baseline heart rate and blood pressure were recorded and then measured every 5 minutes thereafter. Routine estimation, as well as a mathematical model of blood loss calculation, was used to determine intraoperative blood loss.

Main Results: Group N had a significant lower systolic, diastolic, and mean arterial blood pressure than those of group P during the operation. The mean estimated blood loss in group N (443.4 ± 158.0 mL) was significantly lower than that in group P (950.0 ± 554.9 mL). The calculated blood loss (622.7 ± 192.4 mL) in group N was also significantly lower than that in group P (1232.1 ± 630.4 mL).

Conclusion: By inducing moderate hypotension, the use of transdermal nitroglycerine decreases intraoperative blood loss and the need for transfusion.

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1. Introduction

Controlled or deliberate hypotension has been widely used to minimize blood loss during major surgeries. Deliberate hypotension is defined as a reduction in systolic blood pressure (SBP) to 80 to 90 mmHg or a reduction in mean arterial pressure (MAP) to 50 to 65 mmHg in normotensive patients [1]. Such a reduction in blood pressure (BP) has the advantage of providing bloodless surgical fields as well as decreasing the need for blood transfusion [2]. Various drugs including volatile anesthetics, direct-acting vasodilating drugs, autonomic ganglionic blocking drugs, α and β adrenergic blocking drugs, and calcium channel entry blocking drugs have been used to induce controlled hypotension and thereby reduce blood loss during such surgeries [1]. All of these drugs were administered intravenously (IV). Nitroglycerine is also available in the form of transdermal dosage. Relative to IV nitroglycerine dosage form, the transdermal form offers the advantage of easy administration and gradual release of active substance [3]. The effects of transdermal nitroglycerine in inducing controlled hypotension and thereby reducing the blood loss during major orthopedic surgery have not been investigated. Therefore, the present study was designed to examine the efficiency of transdermal nitroglycerine in reducing blood loss during open fixation of femur shaft fractures.

2. Materials and methods

The study was performed after we received approval of the local institutional board review in a university-affiliated hospital from January to June 2004. Written consent was obtained. A total of 60 ASA physical status I and II patients (age, 20-60 yrs) scheduled for elective open fixation of femur shaft fracture were enrolled. Patients with ASA physical status greater than II, a history of myocardial infarction or angina pectoris, or a documented coronary artery disease, uncontrolled hypertension, or significant liver and kidney disease were excluded from the study.

Participants were randomly assigned according to computer-generated blocks to receive either nitroglycerine (group N, $n = 30$) or placebo (group P, $n = 30$). The placebo was the base of nitroglycerine ointment without the active ingredient. In all cases, the time elapsed from fracture to operation was not more than one week, and open fixation was performed with plate and screws by the same surgeon.

Upon arrival at the operating room, an IV catheter was inserted into a forearm vein. A sample of blood

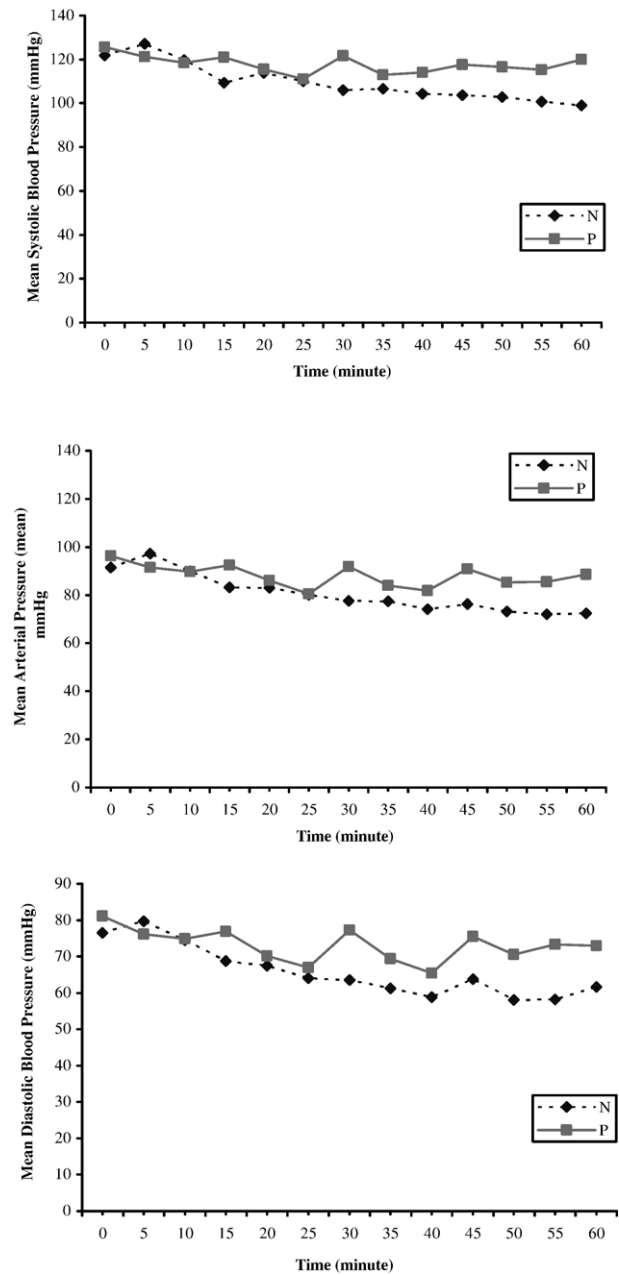


Fig. 1 Comparison of systolic, diastolic, and mean arterial pressure in the nitroglycerine and placebo groups.

was withdrawn for the determination of hematocrit (Hct) (initial Hct).

Afterward, patients received either 7.5 cm of transdermal nitroglycerine (Myovin, CADILA pharmaceutical, India) or 7.5 cm of placebo. The topical ointment contains 20 mg of nitroglycerine per milliliter of ointment, one inch or 25 mm of ointment contains about 15 mg of nitroglycerine [4]. Both nitroglycerine and placebo were of identical color and were applied to the patients' anterior chest walls by a person who was not involved in the rest of study.

Patients were then administered 5 mL/kg of IV fluid (Ringer's or normal saline solution) and were premedicated

Table 1 Demographic data of the patients

Data	Group N	Group P
Age, mean \pm SD, y	31.9 \pm 15.4	32.6 \pm 13.1
Gender, women/men	12/18	9/21
Weight, mean \pm SD, kg	63.70 \pm 11.06	67.40 \pm 10.92
Duration of operation, min	71.8 \pm 10.1	78.5 \pm 10.7

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