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Evaluation of efficacy of Valsalva for attenuating needle puncture pain in first time nonremunerated voluntary plateletpheresis donors: A prospective, randomized controlled trial

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Abstract:

BACKGROUND: Plateletpheresis is generally safe but may have adverse reactions. Adverse reactions can negatively influence donor recruitment and retention. Valsalva is a proven method of attenuating pain caused by venipuncture.

AIMS: The aim was to evaluate the efficacy of the Valsalva maneuver on the attenuation of needle pain and donor anxiety.

SETTINGS AND DESIGN: This prospective randomized controlled trial was conducted between November 2015 and April 2016 at the Department of Transfusion Medicine.

SUBJECTS AND METHODS: One-hundred and sixty consecutive donors were grouped into control group (C) and Valsalva group (V) each of sample size 80. The Valsalva group performed a Valsalva maneuver and control did nothing before the venipuncture. Anxiety and pain were scored using a 10 cm visual analog scale (VAS). Severity was graded as VAS = 0 defines no pain and anxiety, VAS = 1–3 as mild pain and anxiety, VAS = 4–6 as moderate pain and anxiety, VAS = 7–9 as severe pain and anxiety, whereas VAS = 10 denotes extreme pain and anxiety.

STATISTICAL ANALYSIS: Statistical Package for Social Sciences, version 23 was used for analysis. Independent samples *t*-test/Mann–Whitney U-test was used to compare between treatment and control group, whereas the Wilcoxon signed-rank test was used to test the difference between pre- and postobservations.

RESULTS: In the Valsalva group, post-Valsalva anxiety levels were significantly reduced to (1 [0–2]) from their pre-Valsalva values of (2 [0–3]); ($P < 0.001$). Pain was significantly lower (2[1-2]) in Valsalva group compared to control (4[2–5]); ($P < 0.001$).

CONCLUSIONS: Valsalva reduced both severity of venipuncture pain and anxiety. Valsalva can be performed by donors as it is an easy, painless, and nonpharmacological method of pain and anxiety attenuation.

Keywords:

Anxiety, apheresis, needle pain, plateletpheresis donor, Valsalva

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Introduction

Plateletpheresis is considered to be safe with a low incidence of adverse reactions.[1] Local adverse reactions are

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hematomas, pain, swelling, hyperemia, nerve irritation, allergy, and thrombophlebitis, whereas systemic are vasovagal and citrate toxicity.[2,3] Adverse reactions can have a negative effect on donor recruitments and future retention.[3] Among adverse effects, needle puncture pain plays an important impact on donor satisfaction, intention, and repeat donation. It has both psychological and somatic components.[4] The somatic component is vasovagal manifestation. The vasovagal response could also result because of donor anxiety or seeing another anxious donor. Risk factors of developing vasovagal reaction are younger age, inexperienced donor, and smaller body size.[5-7] Adverse reactions can also be due to the donor's psyche or anxiety. Trait anxiety is a person's natural demeanor and state anxiety is a temporary reaction to a stress.[8,9] Women have seen to be more prone to vasovagal reaction than men.[10] Few methods such as local anesthetics and audio-visual distraction have limited therapeutic efficacy on needle pain and donor anxiety.[11,12]

The Valsalva method is a simple pain-alleviating physiological technique with fast onset and without any pharmacological and hemodynamic side effects on subjects. It attenuates venipuncture pain by both somatic and distraction mechanism. It reduces the donor's fear and anxiety along with the enhancement of the donor's coping ability for procedural pain. It is performed by maximal, forceful expiration against a closed glottis for a period of 20 s.[13-17]

However, there is no published study regarding the effect of Valsalva on needle pain and anxiety among blood donors. In order to improve the donor recruitment and retention, the present study was planned to assess the efficacy of the Valsalva maneuver on plateletpheresis donor needle pain as the primary objective and donor anxiety as the secondary objective.

Subjects and Methods

Study design and setting, ethical approval

This open-label, prospective, randomized controlled trial was conducted between November 2015 and April 2016 at the Department of Transfusion Medicine, following institutional ethics committee approval (IE2016-23-IP-90) and donors' written informed consent. The study was registered at the Clinical Trial Registry of India (Ref: CTRI/2018/03/12322).

A total of 160 adults were enrolled as first-time plateletpheresis donors according to the drugs and cosmetic act, 1945.[18]

Inclusion criteria

- Age 18–65 years
- Weight >55 kg
- Hemoglobin level ranging 12.5–18.5 g/dl
- Donors without a history of
  - Typhoid, tattoo, antirabies injection, blood product transfusion, or major surgery within the last 1 year
  - Malaria in the last 3 months
  - Dengue in the last 6 months
  - Jaundice in the last 2 years
  - Fever with cough and cold, antibiotics, or antifungals in last week were included
- Donors with negative status for serum hepatitis, HIV, malaria, and syphilis were 3 acceptable for plateletpheresis
- Capability to perform Valsalva maneuver.

Exclusion criteria

- Subjects not fulfilling inclusion criteria
- Repeat donors
- Donors with abnormal skin conditions like
  - Infection at the proposed venipuncture site
  - Requiring more than one venipuncture attempt or venipuncture site for successful phlebotomy subjects being unable to perform Valsalva maneuver were also excluded.

Sample size estimation

Based on our pilot study, the mean visual analog scale (VAS) of needle pain in the control group of donors was 3 ± 1.5; we assumed pain reduction in the Valsalva group by one-third to be clinically significant to produce a mean VAS of 2 ± 1.62, at minimum two-sided 95% confidence interval and 95% power of the study, the minimum required sample size was 65. After considering possible any dropouts and open-label study design, we included 80 donors in each group. The sample size was calculated using power analysis and sample size software, version-8 (PASS-, NCSS Statistical Software, USA).

Randomization, study intervention, and blinding

Total 160 consecutive eligible donors were included. Each donor was given a specific serial number between 1 and 160. The first computer-generated random number was drawn using www.randomization.com by the project resident (junior resident) and accordingly, 80 donors were randomly allocated in the Valsalva group (V) and 80 in the control group (C) [Table 1 and Figure 1]. In the waiting area, the phlebotomy registrar (senior resident) explained about how to perform the Valsalva maneuver to the donors of the Valsalva group [Table 1]. A staff nurse was taught about the VAS scale. After ensuring proper training, the nurse was exclusively allotted for the measurement and noting down the anxiety and pain score of donors

on the VAS scale [Table 1]. She was also assigned to monitoring and recording of vitals [Table 1]. Donors could not be blinded so it is an open-label study; otherwise, project residents, phlebotomy registrar, nurse staff, and analysts all were kept blinded to study.

Donors were scheduled between 9 and 11 am donation slot. After shifting the donors to the donation area, they were laid supine on the donation couch after installing the plateletpheresis kit (Fenwal amicus, Fresenius Kabi, Germany). Pulse rate (PR) and mean blood pressure (MAP) were noted. Preintervention anxiety was scored using a 10 cm VAS scale by the staff nurse, after which she left the room. Donors in the Valsalva group were asked to blow into a rubber tubing connected to a sphygmomanometer and raise the mercury column up to 30 mmHg for a period of at least 20 s, immediately before needle puncture in a cubital fossa with better venous access. Donors of the control group did not perform Valsalva.

Table 1: Project work assignment

Person assigned	Task
Project resident	Junior resident, took consent, computer-generated randomization, part of study, blinded about grouping
Phlebotomy registrar	Senior resident explained how to perform Valsalva maneuver
	Did phlebotomy procedure
	Not part of study, blinded
Staff nurse	Measured and noted down the anxiety and pain score of donors
	Vital monitoring and recording
	Blinded to the study
Statistician	Data analysis
	Blinded to the study

After the group-specific intervention, venipuncture was done by the dedicated phlebotomy registrar with a 17G needle [Table 1]. Post intervention, the staff nurse was asked to note down the needle pain felt by the donor on the VAS scale and also anxiety score [Table 1]. VAS is a unidimensional pain rating scale comprising of a 10 cm line, anchored by no pain or anxiety (0) and worst pain or anxiety (10).

The inlet line drew blood into the machine (extracorporeal volume [ECV]) and in each cycle, platelets were collected along with a certain amount of plasma into a platelet bag. After each cycle, blood was returned to the donor

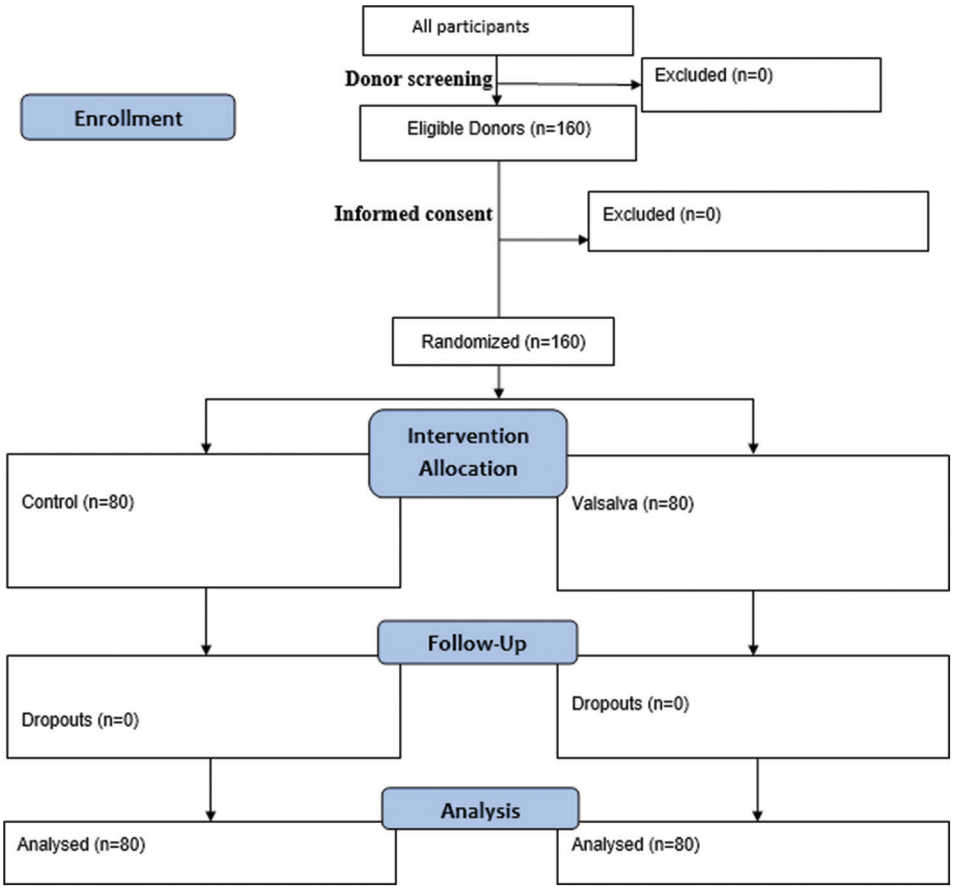

Figure 1: Flow chart of donor study. A total of 160 participant adults were assessed for eligibility as a donor. Consented 160 donors were randomized and allocated into two groups with 80 assigned to control group (C) and 80 to Valsalva group (V). There were no dropouts and exclusions. All donor's data were analyzed

through the return line. Oral calcium supplementation was routinely given during the procedure and vital monitoring (PR and MAP) was done. At the end of the procedure, the needle was removed from the donor arm. After ensuring donors' well-being, they were escorted to the waiting area for refreshment and observation of 20–30 min for any adverse reactions.

Primary and secondary objectives

The primary objective was to evaluate the efficacy of the Valsalva procedure on the reduction of needling pain in plateletpheresis donors. Secondary objectives were to evaluate the efficacy of the Valsalva procedure on the reduction of donor anxiety and comparison of pain severity between male and female donors.

Outcome measures and assessment

The primary outcome was the severity of needle pain; the secondary outcome was the severity of donor anxiety. All these outcomes were measured by a staff nurse kept blind to the study The VAS scale is a continuous scale of 0–10 cm, being self-completed by the donor. Donors were asked to mark on the VAS line at the point representing their intensity of pain and anxiety. The staff nurse used a ruler to measure the distance on this 10-cm line between the "no pain" anchor and the donor's mark.

Severity was graded as VAS = 0 defines no pain and anxiety, VAS = 1–3 as mild pain and anxiety, VAS = 4–6 as moderate pain and anxiety, VAS = 7–9 as severe pain and anxiety, whereas VAS = 10 denotes extreme pain and anxiety.

Statistical analysis

The normality of the continuous data was tested, and a variable was considered normally distributed when the standard deviation (SD) was less than half of the mean. Continuous normally distributed variable was presented in mean ± SD while ordinal data as the median and interquartile range (IQR).

To compare the means, median, and proportions between Valsalva and control groups, independent samples *t*-test or Mann–Whitney U test or Chi-square test was used as appropriate. To test the change in distributions between pre–post observations when the score was in ordinal scale, the Wilcoxon signed-rank test was used. $P < 0.05$ was considered as statistically significant. Statistical package for social sciences, version 23 (SPSS-23, IBM, Chicago, IL, USA) was used for analyzing the data.

Results

Donors characteristics

The total included 160 screened donors were enrolled with 80 being randomly assigned to the control group (C) and 80 to Valsalva group (V). All 160 completed study. Data of 160 (100%) donors were analyzed [Figure 1]. All donors were male. The mean age of donors was 32.98 ± 10.62 and 33.08 ± 10.66, mean height 170.44 ± 7.75 and 170.96 ± 7.20, mean weight 72.04 ± 11.17 and 72.71 ± 11.12, and body mass index were 24.94 ± 4.62 and 24.93 ± 3.88 in control and Valsalva groups. Demographic characteristics showed no statistically significant difference between the two groups ($P > 0.05$) [Table 2].

Donors' needle pain

The incidence of needle pain was 100% in both groups. Intensity of needle puncture pain (median [IQR]) was significantly lower in Valsalva group compared to control group (2 [1–2] vs. 4 [2–5], $P < 0.001$) [Table 3]. Hence, venipuncture pain was mild in the Valsalva group compared to moderate in the control group.

Donors' anxiety

Table 4 lists the anxiety level comparison of the control group and pre-Valsalva and post-Valsalva of the study group. In the Valsalva group, post-Valsalva median anxiety value was significantly lowered compared to their own anxiety values pre-Valsalva (1 [0–2] vs. 2 [0–3]), $P < 0.001$). Similarly, the mean anxiety score was significantly lower in the post-Valsalva phase of the Valsalva group as compared to the control group (1.01 ± 1.11 vs. 1.8 ± 1.89, $P = 0.016$). The mean value of anxiety score was compared as median values were similar. Anxiety scores in pre-Valsalva phase of Valsalva group were similar to the control group ($P = 0.157$).

Table 2: Donors' characteristics

Donor	Control (*n*=80)	Valsalva (*n*=80)	*P*
Age (years)	32.98±10.62	33.08±10.66	0.953[#]
Sex (male/female)	80/0	80/0	0.999[$]
Height (cm)	170.44±7.75	170.96±7.20	0.660[#]
Weight (kg)	72.04±11.17	72.71±11.12	0.702[#]
BMI	24.94±4.62	24.93±3.88	0.985[#]

Values are presented as mean±SD or frequency (%). [#]Independent samples *t*-test/[$]Fisher's exact test used. SD=Standard deviation, BMI=Body mass index

Table 3: Severity of venipuncture pain

Groups	Mean±SD	Median (IQR)	*P*
Valsalva (*n*=80)	1.75±0.92	2 (1-2)	<0.001
Controls (*n*=80)	3.62±1.46	4 (2-5)	

Mann–Whitney U-test used. Values are presented as median (IQR) and mean±SD. SD=Standard deviation, IQR=Interquartile range

Table 4: Severity of anxiety of pre- and post-Valsalva phase of Valsalva with control group

Groups	Median (IQR)	Mean±SD
Control	1 (0-2.75)	1.8±1.89
Valsalva (pre)	2 (0-3)	2.11±1.80
Valsalva (post)	1 (0-2)	1.01±1.11

[$]Pre- versus post-Valsalva: $P<0.001$, [#]Control versus pre-Valsalva: $P=0.157$, [#]Control versus post- Valsalva: $P=0.016$, [$]Wilcoxon signed-rank test/[#]Mann–Whitney U-test used. Values are presented as median (interquartile range) and mean±SD. SD=Standard deviation, IQR=Interquartile range

Vitals

Table 5 shows that there was no significant change in PR and MAP throughout the plateletpheresis in the two groups ($P > 0.05$). Intragroup comparison of PR was significant in both groups on repeated measures analysis of variance test. PR change was significant in both Valsalva group and control group at intervals of 0 to 15 and 15 to 90 min. Conclusively, it appears that there is no added role of the Valsalva maneuver over the control group in respect to PR change. Intragroup comparison of MAP at different intervals was not significant statistically in both groups ($P > 0.05$). There was also no significant change in hemodynamic vitals (PR and MAP) throughout the 90 min of plateletpheresis between the two groups ($P > 0.05$).

Other adverse events

There was no incidence of local hematoma, citrate toxicity, allergy, nerve irritation, tingling, numbness and paresthesia bradycardia, hypotension, or vasovagal reaction.

Discussion

Donor's needle pain

Our study had shown that the Valsalva maneuver significantly reduced the severity of needle pain in plateletpheresis donors. Valsalva maneuver is a proven physiological method being effective in reducing the severity of venipuncture pain.

Added reduction in needle pain could be directly due to Valsalva induced anxiolysis. Pain and anxiety influence future donation intention directly and indirectly both.[19]

We observed that Valsalva performed before venipuncture reduced both severity of venipuncture pain and anxiety related to plateletpheresis procedure in the Valsalva group as compared to the control group. Pain reduction could be possibly due to both the distraction mechanism and the sino-aortic baroreceptor reflex arc mediated antinociceptive mechanism.

Donor's anxiety

The Valsalva group had shown that post-Valsalva anxiety level was significantly lower than their corresponding pre-Valsalva and control group. Additional advantage in the Valsalva group could be of being properly instructed about Valsalva before the intervention and efficiently performed Valsalva maneuver by donors. Hence, Valsalva can have a direct positive effect on donor satisfaction by anxiolysis. In this way, Valsalva can positively affect donation retention. Similar results were shown in an analysis done by France *et al*.[19] Donor compliance-based methods are necessary for the success of the donation process and donation intention. These methods include new predonation materials, standard work guidelines for staff, keeping the view of needle puncture area away from donor's waiting room, water drinking by donors 30 min before needle puncture, and performing leg lifting.[7,20-22] These methods work by boosting the confidence of donors in their ability to cope with the donation process and increasing donation tendency irrespective of their effect on donor anxiety.[19] Likewise, Valsalva is also dependent on donor compliance and boosts donor confidence for future donation through its anxiolytic effect.

Valsalva maneuver and its analgesic mechanism

Valsalva-induced analgesia is by peripheral activation of sino-aortic baroreceptor reflex arc, central inhibition of pain conduction, and raised circulatory noradrenaline.

Distraction has been used for reducing the distress of the immediate surrounding during venipuncture.[23] Distraction methods such as movies and balloon inflation have played a role in needle pain attenuation.[13,14] Similarly, the results of our Valsalva maneuver concur with the previous studies stating reduction in fear and anxiety by techniques such as visual distraction, prehydration, and muscle tension caused improved donor coping capability, donor satisfaction, retention, and likelihood to return for donation.[7,12,21,22]

Table 5: Vitals (pulse rate and mean arterial pressure) comparison between Valsalva and control group

	Baseline	15 min	30 min	90 min	*P*
PR					
Valsalva (*n*=80)	78.79±7.85	76.79±7.96	77.76±7.64	78.2±7.84	0.078
Control (*n*=80)	76.60±6.71	74.88±7.19	75.63±7.51	76.39±6.42	0.118
P	0.060	0.113	0.076	0.112	
MAP					
Valsalva (*n*=80)	78.83±8.08	79.30±8.20	79.09±8.40	79.41±8.21	0.243
Control (*n*=80)	78.25±8.05	77.80±7.80	78.83±7.74	77.05±8.56	0.228
P	0.653	0.237	0.837	0.077	

Values are presented as mean±SD. PR_0, PR_{15}, PR_{30}, and PR_{90}. And MAP_0, MAP_{15}, MAP_{30}, and MAP_{90} represent PR and MAP at baseline and 15, 30, and 90 min. Independent samples *t*-test was used to compare between Valsalva and control groups. Repeated measures ANOVA used within Valsalva and control group. PR=Pulse rate, MAP=Mean arterial pressure, SD=Standard deviation, ANOVA=Analysis of variance

Apheresis-related adverse reactions

Longer apheresis procedure with mechanical and mental factors due to produced noise and vibration by CS3000 apheresis machine along with needling of both arms made the donors apprehensive and prone to a vasovagal reaction.[2] In our study, a vasovagal reaction was negligible in both groups. Reasons could be the shorter duration of plateletpheresis procedure itself, Fenwal amicus apheresis machine with continuous flow, and studied donors being of male gender and of age 18 years and above.

The incidence of hematoma was nil as the phlebotomist was a dedicated trained registrar and selected veins were prominent. A less experienced phlebotomist with poor skill and poorly visible vein selection has usually been the reason for local hematoma formation.[2]

There was no incidence of hypotension in our study. It could be due to multiple factors such as male donors, Valsalva-induced anxiolysis, continuous flow apheresis machine, and low ECV.

The incidence of tingling, numbness, and paresthesia was also negligible in both the groups, possibly because of routine calcium tablet supplementation during the plateletpheresis, dilution of citrate in returning blood from the apheresis instrument to the donor, rapid metabolism of citrate by kidney, liver, and muscle leading to unbinding of calcium.[2]

Study limitations

Our study had a few limitations. Due to the open-label study, there is some limitation, although we had tried to minimize it by increasing the sample size. No comparison could be made between the genders as the groups consisted of only males, leaving the secondary objective unfulfilled. The effect of the Valsalva maneuver on pain attenuation was not substantiated by biomarkers leveling. Future studies can be conducted to validate the Valsalva procedure using biomarkers.

Conclusions

Valsalva reduces both severity of needle pain and anxiety associated with the plateletpheresis with a positive influence on donation satisfaction, intention. Valsalva could be performed routinely in all donation programs being cost-effective, easy to perform, painless, donor motivating, and nonpharmacological analgesic and anxiolytic maneuver.

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Conflicts of interest

There are no conflicts of interest.

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