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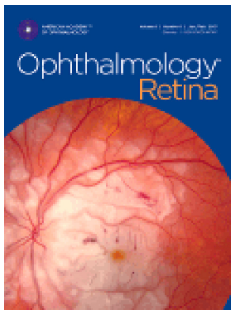

Nonsupine positioning after macular hole surgery. A prospective multicenter study

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PII: S2468-6530(18)30649-3

DOI: https://doi.org/10.1016/j.oret.2018.12.006

Reference: ORET 444

To appear in: *Ophthalmology Retina*

Received Date: 20 October 2018

Revised Date: 20 December 2018

Accepted Date: 24 December 2018

Please cite this article as: Lindtjørn B., Krohn J., Austeng D., Fossen K., Varhaug P., Basit S., Helgesen O.H., Eide G.E. & Forsaa V.A., Nonsupine positioning after macular hole surgery. A prospective multicenter study, *Ophthalmology Retina* (2019), doi: https://doi.org/10.1016/j.oret.2018.12.006.

Nonsupine positioning after macular hole surgery. A prospective multicenter study

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Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Competing interests: None of the authors have any conflicting interests to disclose.

Running head:

Lindtjørn et al: Nonsupine positioning after MH surgery

Key words: face-down positioning, intraocular gas, macular hole, nonsupine positioning, postoperative positioning, prone positioning, prospective study

ABSTRACT

Purpose: To evaluate the postoperative closure rate of full-thickness macular holes (MH) after nonsupine positioning, which means that the patients avoid upward gaze and a supine sleeping position, and to investigate the correlation between postoperative positioning compliance and closure rate.

Design: Prospective, multicenter study. (ClinicalTrial.gov: NCT02295943).

Participants: Patients undergoing primary surgery for primary MH.

Methods: Patients underwent pars plana vitrectomy with internal limiting membrane peeling and SF_6 gas tamponade followed by 3–5 days of nonsupine positioning. A "positioning measuring device" which recorded the time in supine position, was attached to patients' forehead postoperatively for 24 hours.

Main Outcome Measures: Anatomical closure rate of MH at two weeks or more after surgery, and the time spent in supine position during the first 24 hours postoperatively.

Results: A total of 205 participants were included of which two were lost to follow-up. Two hundred and two out of 203 MH closed after a single operation giving a closure rate of 99.5% (95% confidence interval: 97.3–99.9%). The median time of supine positioning during the first 24 hours was 29 seconds (range, 0:00:00–01:52:28). Because of the very high closure rate, a correlation between positioning compliance and closure rate could not be established.

Conclusion: Pars plana vitrectomy with internal limiting membrane peeling followed by a short-term nonsupine positioning accomplished a very high MH closure rate. Thus, face-down positioning was not necessary to achieve excellent closure rates in this study.

Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article.

Full-thickness macular hole (MH) has an incidence of 7.9 eyes per 100 000 inhabitants per year, and the condition has a significant impact on the quality of life of affected individuals.[1, 2] Surgery normally consists of pars plana vitrectomy (PPV), peeling of the internal limiting membrane (ILM) and insufflation of an intraocular gas. The main effect of the gas tamponade is to isolate the MH from intraocular fluid. This in turn allows for absorption of the subfoveal fluid by the retinal pigment epithelium, and finally fusion of the retinal edges.[3] Face-down positioning ensures the MH being sufficiently isolated from the intraocular fluid. However, the postoperative face-down regimen is challenging for the patients, and strict patient compliance is rarely achieved.[4, 5] Since Tornambe et al. in 1997 reported successful surgery of MH without postoperative face-down positioning,[6] there is growing evidence supporting a postoperative regimen where the patients avoid upward gaze and a supine sleeping position.[7-10]

The most critical period following surgery occurs within the first 24 hours, in which 82% of the MH close.[11] If a MH does not close during the first 3 days, it is likely to remain open.[12] We consider a continuous gas–foveal contact during the first postoperative 24 hours to be essential to achieve MH closure. This point is supported by our previous study on air tamponade in combination with a nonsupine positioning (NSP) regimen where only 70% of MH closed.[11] Possibly, the rapid absorption of intraocular air allowed early contact between the intraocular fluid and the hole, leading to an interrupted healing process.

There is probably a threshold for the duration a MH can be in contact with fluid without interfering with the healing and closure of the hole.

Patients who for some periods of time position themselves supine, will have a longer fluid–foveal contact than compliant patients. By measuring the time spent in supine position, hereafter called “supine time”, we obtained an indirect measurement of the fluid-foveal contact. The main objectives of the present study were to evaluate the MH closure rate after a NSP regimen, and to investigate the correlation between the closure rate and the duration of fluid–foveal contact.

Methods

Study Design and Participants

This prospective multicenter study was conducted at the Departments of Ophthalmology at Stavanger University Hospital, Haukeland University Hospital, Trondheim University Hospital, and the University Hospital of North Norway between December 2014 and November 2017. We obtained informed written consent from all participants. The study was approved by the Regional Committee for Medical and Health Research Ethics, South-East Norway and complied with the tenets of the Declaration of Helsinki. At ClinicalTrials.gov the study was registered with the registration number NCT02295943.

Inclusion criteria were primary MH, duration of symptoms of less than 24 months and informed written consent. Exclusion criteria were previous vitrectomy, secondary MH, myopia greater than 6 diopters, and age younger than 18 years. The primary outcome measure was primary anatomical closure of the MH assessed by optical coherence tomography (OCT) two weeks or more after surgery.

Ophthalmologic Examination and Surgical Procedures

Preoperative examination consisted of visual acuity (VA), Goldmann applanation tonometry, slit lamp biomicroscopy, fundoscopy, and OCT imaging of the macula. Visual acuity was measured using Early Treatment Diabetic Retinopathy Study (ETDRS) or Snellen charts. When a Snellen chart was used, VA was converted to logarithm of the minimum angle of resolution (logMAR) for statistical analysis.[13] The participants were also asked for their preferred sleeping position, and the investigators scored the expected patient compliance to the forthcoming postoperative positioning regimen on a 4-point scale (0 = no compliance, to 3 = very high compliance). This scoring of expected patient compliance was based on a purely subjective evaluation of the study participants' behavior and response during the preoperative examination. The size of the MH was defined as its minimum horizontal linear diameter (MLD) and classified according to the International Vitreomacular Traction Study (IVTS) Group classification.[14]

Ten experienced surgeons performed the surgeries which consisted of a standard three-port PPV with induction of posterior hyaloid separation and dye assisted peeling of the ILM. Subsequently, the diameter of the ILM peeling was estimated in optic disc diameters before intraocular SF_6 (26–30%) was installed. In phakic patients, the decision to do a phacovitrectomy or a sole vitrectomy, was made by the surgeon.

Immediately after the surgery, a "positioning measuring device" was attached to the patient's forehead as previously described.[15] Briefly, this device consists of a tilt switch connected to a watch, capable to record the accumulated time the patient has kept the head in supine position. If a patient positioned face down, the measuring device was not activated and the time spent in face down position was recorded as NSP. The patients were instructed to follow a NSP regimen, which meant that they could maintain their daily activities, but had to avoid upward gaze and a supine sleeping position at any time

for 3–5 days postoperatively. Based on the surgeon's preference, the so-called tennis ball technique (TBT) could be applied. The TBT regimen consisted of a tennis ball attached to the back of the nightshirt during sleep to prevent the patient from sleeping in a supine position. No patients were instructed to position face-down.

On the following day, approximately 24 hours after surgery, the total time the patient had spent in is supine position was recorded. The patients' compliance was categorized into three levels as described earlier.[15] Compliant, with less than 1 minute supine time, moderately compliant with 1 to 30 minutes, and non-compliant with more than 30 minutes supine time. Two weeks or more postoperatively, OCT verification of MH closure and measurement of VA were obtained.

Statistical Analysis

The power analyses on sample size were calculated using SPSS SamplePower 3.0. Preliminary data on the 24 first subjects from an earlier trial on NSP served as the basis for the power analysis.[15] Mean supine time in that sample was 6 minutes and 34 seconds, and the threshold for non-compliance to the NSP regimen was set to 30 minutes. These data were then log transformed for the power analysis to 4.4 and 7.5, respectively. One goal of the study was to test the null hypothesis that there is no relationship between predictor 1 (supine time) and the closure rate. Under the null, the closure rate (0.90) is the same at all values of predictor 1. Or, equivalently, the odds ratio is 1.0, the log odds ratio (beta) is 0.0, and the relative risk is 1.0. Power was computed to reject the null under the following alternate hypotheses. For Predictor 1 values of 4.4 and 7.5, the expected closure rates are 0.90 and 0.80. This corresponds to an odds ratio of 0.44, beta (log odds ratio) of -0.26, and a relative risk of 0.89. This effect was selected as the smallest effect that would be important to detect, in the sense

that any smaller effect would not be of clinical or substantive significance. It was also assumed that this effect size was reasonable, in the sense that an effect of this magnitude could be anticipated in this field of research. In these computations, we assumed that the mean Predictor 1 value would be 4.4 with a standard deviation (SD) of 2.0, and that the event rate at this mean would be 0.90. The significance level(alpha) was set at 0.05 with a 2-tailed test. For this distribution (Predictor 1 mean of 4.4, standard deviation of 2.0), baseline (event rate of 0.90 at the mean), effect size (log odds ratio of -0.26), sample size (320), and alpha (0.05, 2-tailed), power is 0.80.

Mann–Whitney's U test was used for comparisons between groups containing continuous variables and the chi-squared test was used for comparing categorical variables. The Wilcoxon signed-rank test was used to compare pre- and postoperative VA and the Spearman's correlation to compare the investigators preoperative compliance scoring and actual supine time. A two-tailed *P* value ≤ 0.05 was considered statistically significant. Statistical analyses were made using SPSS statistics, software version 24 (SPSS Inc., Chicago, IL).

Results

Participants

Between December 2014 and June 2017, 205 participants with MH were enrolled in the study. In four patients, the recorded supine time was considered unreliable, as the positioning monitoring device loosened during sleep in three patients and was accidentally removed during morning care in one patient. Consequently, 201 patients had valid measurements of the supine time during the first 24 hours after surgery. One patient was lost to follow-up due to a stroke, and we were not able to determine if this patient's MH had closed. Another patient was examined too early after surgery, failing

to meet the primary endpoint. This patient was therefore excluded from the closure rate calculation, even though the hole was closed at the examination 10 days after surgery. We were able to obtain postoperative OCT imaging and VA measurements in 204 patients, of which 203 met the criteria for the primary endpoint.

Table 1 summarizes the baseline and perioperative characteristics. The mean (SD) age was 69.8 (6.5) years and the mean (SD) duration of symptoms was 6.3 (4.6) months. Based on their MLD, 51% of the MH were classified as large (> 400 µm), 32% as medium (> 250 – ≤ 400 µm) and 17% as small (≤ 250 µm). All patients were instructed to adhere to the NSP regimen, whereas 131 of them combined it with the TBT.

Anatomical Results

Two hundred and two out of 203 MH were closed after primary surgery, which corresponds to a closure rate of 99.5% (95% CI: 97.3 – 99.9 %) (Table 2). Given the planned sample size of 320 participants, the very high closure rate of the 205 enrolled patients made it unlikely that we would be able to determine any correlation between the supine time and the closure rate. For that reason we decided to terminate the study.

Patient Compliance

The overall median supine time for the first 24 hours after surgery was 29 seconds (mean, 00:07:07; range, 00:00:00 – 01:58:28). Without the use of the TBT, the median supine time was 1 minute and 21 seconds (mean, 00:11:07; range, 00:00:00 – 01:47:48) compared to only 19 seconds (mean, 0:04:48; range, 00:00:00 – 01:52:28) with the TBT (P = 0.02).

Compliance Scoring

The investigators' preoperative scoring of patient compliance on the 4-point scale correlated significantly with the patients' actual compliance (r = -0.301, $P < 0.01$) (Figure 1). There was no significant difference between the patients' self-reported preferred sleeping position (supine, face-down or side) and their supine time.

Functional Results

Median VA improved significantly with 3.8 ETDRS lines (mean, 4.0; range, -1.0–14.8) from logMAR 0.7 (mean, 0.7; range, 0.15–1.8) to logMAR 0.3 (mean, 0.3; range, -0.11–1.48) during the study ($P < 0.001$) (Table 2). This is approximately equivalent to an improvement in Snellen VA from 20/100 to 20/40. The majority of patients (78.1%) gained more than two ETDRS lines.

Discussion

We have studied the MH closure rate after surgery, when using a NSP regimen. Unfortunately, a sample size of 205 patients of whom 203 patients had a closure rate of 99.5%, was not sufficient to determine any correlation between the time spent in supine position and the MH closure rate. We assumed that enrollment of another 115 patients would not alter the study's ability to meet its endpoint, and the study was therefore terminated after the enrollment of 205 patients. To investigate a correlation between supine time and MH closure is not practicable when the closure rate approximates 100%. The rationale for anticipating a 90% closure rate in the present study lies in the result of other prospective trials, where the closure rates after surgery with ILM peeling range between 84% and 93%.[10, 16-19] Moreover, prospective multicenter studies with many participating surgeons are likely to

achieve inferior results compared to other studies, as was the case in a previous study on retinal detachment.[20] With this in mind, it was surprising to achieve the extraordinary high closure rate of 99.5%.

All patients were instructed to avoid upward gaze and a supine sleeping position postoperatively for 3–5 days. Therefore, this study provides strong evidence for abandoning the unpleasant face-down positioning regimen after MH surgery. Our results confirm the finding by Tadayoni et al. and Alberti and la Cour, who in randomized controlled studies showed that postoperative NSP was non-inferior to face down positioning.[7, 10] The present study was not randomized, which may weaken the impact of our findings. Nevertheless, given such a high closure rate, a randomized trial would probably have limited additional value.

The TBT regimen led to a significantly shorter median supine time during sleep with 00:00:19 compared to 00:01:21 in the group not following the TBT regimen. Although our study was not designed to investigate the comparison of NSP and NSP-TBT, this finding confirms the results of an earlier study on postoperative positioning compliance.[15] In the present study, the difference in compliance did not have any effect on the closure rate. According to a study by Alberti and la Cour, intraocular fluid interrupted the gas–foveal contact with a median of 44 times over 24 hours in the setting of a NSP regimen.[21] Consequently, several minor interruptions of the gas–foveal contact do not substantially interfere with MH closure. Two possible reasons for the low impact of such interruptions on the healing process need attention. First, when the gas–foveal contact prevents influx of fluid into the retina, the retinal pigment epithelium pump effectively reduces the intraretinal edema and facilitates fusion of the MH edges.[22] Minor interruptions of the gas–foveal contact are probably too short to allow intraocular fluid to accumulate in the retinal tissue and keep the MH open.

Consequently, there could be some tolerance for fluid during the process of MH closure. Second, MH may already have sealed prior to these interruptions. As reported by Kikushima et al, the postoperative healing process starts immediately, and they observed closure of MH as soon as 20 minutes after surgery.[23] In the present study, the time interval from surgery to bed-time was likely to exceed eight hours. It is thus likely that some of the MH had already closed before the patients went to sleep, making the nocturnal positioning compliance irrelevant. This could also explain the fact that in 15 (7.5%) of the patients, the MH closed despite more than 30 minutes (range, 00:34:17 – 01:52:28) in supine position. In these cases, longer periods of contact between the MH and the intraocular fluid seemed to be well tolerated.

The investigators' subjective preoperative scoring of the patients' positioning compliance proved to correlate significantly with their actual compliance. With this in mind, it makes sense to enhance the patient's ability to follow the NSP regimen by means of the TBT in those who are assumed to have a low level of compliance.

To our knowledge, this is the largest prospective study on positioning of patients after MH surgery to date. It demonstrates that a short-term NSP regimen combined with a short acting intraocular tamponade like SF_6, is probably sufficient to obtain excellent closure rates. A tennis ball attached to the back of patients' nightshirt is a useful tool to support patient compliance. Further studies are needed to understand the process of MH closure in relation to interruptions of the gas–foveal contact.

Acknowledgements

The authors thank Mr. Kenneth Juvik and Mr. Rolf Haakonsen at the Clinical Engineering Department, Haukeland University Hospital, for manufacturing the

positioning monitoring device. We also thank MD Laila Tjelta Hashemi, MD Nils-Erik Boonstra, MD Erlend Ulltang and MD Nina Krøll Angelsen for helping with inclusion, treatment, and follow-up of study participants.

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Figure Legends

Figure 1.

Box plot illustrating the three groups of assumed compliance scored by the investigators during the preoperative examination, and the actual supine time after surgery. The length of the box indicates the interquartile range (IQR) and the whiskers represent the 1.5 IQR. The line within the box shows the median. Outliers are indicated with a circle (o), and extreme outliers are indicated with an asterisk (*)

Table 1.

Baseline and perioperative characteristics of the study participants.

Parameters	Entire cohort (*n* = 205)
Male, no. (%)	71 (35)
Age, mean (SD), years	69.8 (6.5)
Pseudophakia, no. (%)	41 (20)
Duration of symptoms, mean (SD), months	6.3 (4.6)
Preoperative VA, median	
logMAR (range)	0.7 (0.2 – 1.8)
Snellen	20/100
MLD, mean (SD), µm	411 (161)
BD, mean (SD), µm	850 (268)
MH size, no. (%)	
Large (> 400 µm)	105 (51)
Medium (> 250 – ≤ 400 µm)	66 (32)
Small (≤ 250 µm)	34 (17)
VMT, no. (%)	65 (32)
ERM, no. (%)	63 (31)
Phakovitrectomy, no. (%)	147 (72)
SF_6 concentration, median (range), vol%	30 (26 – 30)
Diameter of ILM peeling, median (range), ODD	2.25 (1.0 – 4.5)
Type of dye used for ILM peeling, no. (%)	
Indocyanine green	60 (29)
Brilliant blue G	87 (42)
Trypan blue	58 (28)

BD = base diameter; ERM = epiretinal membrane; ILM = internal limiting membrane; logMAR = logarithm of the minimum angle of resolution; ODD = optic disc diameter; MH = macular hole; MLD = minimum linear horizontal diameter; SD = standard deviation; VA = visual acuity; VMT = vitreomacular traction.

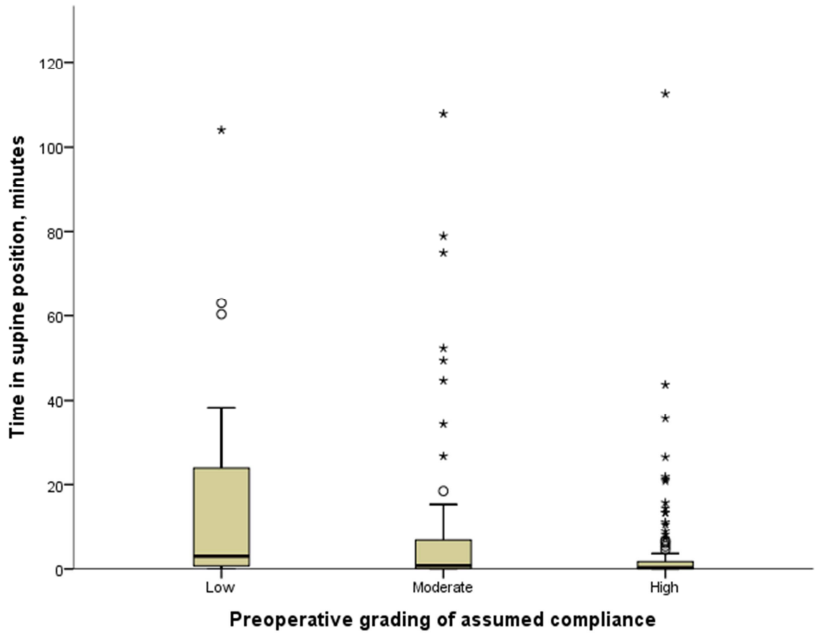
Table 2.

Anatomical and functional results.

	Cohort	NSP	NSP with TBT	*P*	n*
MH closure, no./no. (%)	202/203 (99.5)	74/74 (100)	128/129 (99.2)	0.45	203
Time in supine position, hh:mm:ss					
Median (range)	00:00:28 (00:00:00 – 01:52:28)	00:01:21(00:00:00 – 01:47:48)	00:00:19 (00:00:00 – 01:52:28)	0.002	201
Mean (SD)	00:07:07 (00:18:03)	00:11:07 (00:23:09)	00:04:48 (00:13:51)		
Median postoperative VA					
logMAR (range)	0.3 (-0.1 – 1.5)	0.3 (0.0 – 1.5)	0.3 (-0.1 – 1.2)	0.40	203
Snellen	20/40	20/40	20/40		
VA gain, median (range), ETDRS lines	3.8 (-1.0 – 14.8)	3.0 (0.0 – 14.8)	4.0 (-1.0 – 11.8)	0.11	203
SRF, no./no. (%)	63/191 (33.0)	25/74 (33.8)	38/117 (32.5)	0.85	191
Median time to last examination, weeks (range)	5 (2 – 111)	5 (2 – 23)	5 (2 – 111)	0.01	203

ETDRS = Early Treatment Diabetic Retinopathy Study; logMAR = logarithm of the minimum angle of resolution; MH = macular hole; NSP = nonsupine positioning; SD = standard deviation; SRF = subretinal fluid; TBT = tennis ball technique; VA = visual acuity.
* Number of analyzed eyes.

Figure 1



Précis

This large, prospective multicenter study shows that uncomfortable postoperative face-down posturing is unnecessary for successful macular hole surgery.