



Does an intensive alcohol cessation intervention at the time of fracture surgery induce smoking cessation? - The Scand-Ankle study

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Abstract

Background Hazardous alcohol consumption is a risk factor for developing postoperative complications. Other risk factors are smoking, overweight, malnutrition and physical inactivity. Preoperative alcohol and smoking cessation programs have been found effective in reducing postoperative morbidity, but it remains unknown whether these induce a general change of lifestyle. The aim of this study was to investigate whether the gold standard alcohol intervention programme (GSP-A, which is based on the gold standard programme for smoking GSP-S) used in the Scand-Ankle study, affected the non-targeted risk factors; smoking, overweight, malnutrition and physical inactivity.

Method 64 patients with hazardous alcohol consumption who underwent ankle fracture surgery, were randomized to the GSP-A or usual care (control). The groups were compared at baseline and 6 weeks follow-up regarding lifestyle factors. An intention to treat (ITT) and per protocol analysis were performed using non-parametric statistics.

Results The ITT-analysis showed no significant differences between the GSP-A and control group regarding non-targeted risk factors. The per protocol analysis showed that alcohol cessation regardless of study group did not influence non-targeted risk factors.

Conclusion The GSP-A did not affect smoking, overweight, malnutrition and physical inactivity. Thus, a potential effect of the GSP-A on postoperative complications will likely be due to the effect on alcohol intake and not a general change in lifestyle. The findings suggest that multiple lifestyle interventions are required, e.g. combined alcohol and smoking cessation.

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Introduction

High alcohol consumption is a major risk factor for post-operative complications, including general infections, wound complications, pulmonary complications, prolonged hospital stay and increased mortality (1). In addition to hazardous drinking it is well-known that smoking, being overweight, malnutrition and physical inactivity also constitute major risk factors for post-operative complications (2-9). Intensive preoperative alcohol and smoking cessation intervention programs have been found to be effective at reducing postoperative complications and morbidity (10;11). Further, a postoperative smoking cessation intervention has also shown a beneficial effect on postoperative complications following acute fracture surgery (12).

Alcohol consumption and smoking are known to be associated with one another,

with smokers drinking more alcohol than non-smokers (13-15), and heavy drinking being associated with heavy smoking (16). However, it is still unclear to what extent alcohol interventions affect non-targeted risk factors as smoking. To our knowledge the effect of intensive alcohol intervention in a surgical setting on other non-targeted lifestyle factors has not previously been investigated. The aim of this study was therefore to investigate whether the gold standard programme for alcohol cessation (GSP-A) induced smoking cessation, and also whether or not it had an effect on overweight status, risk of malnourishment and physical inactivity. Our hypothesis was that the GSP-A, targeting alcohol consumption, would result in a healthier lifestyle in general. The GSP-A has been proven effective on alcohol cessation in the setting of this study; 58% of the patients stopped drinking for 6 weeks in the GSP-A group vs. 13% in the control group (17).



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Methods

Study design

This is a sub-study of the Scand-Ankle study, which is an ongoing randomized clinical trial (RCT) that investigates the effect of a new GSP-A on postoperative complications, alcohol intake and cost-effectiveness in hazardous drinking patients undergoing ankle fracture surgery (ClinicalTrials.gov Id: NCT00986791).

Inclusion and exclusion criteria

Patients were included if they during the past three months had an alcohol consumption of ≥ 21 units/week (one unit equals 12 g of ethanol), were undergoing ankle fracture surgery, and gave informed consent for participation within 36 hours of admission.

Patients were excluded if they were under the age of 18 or otherwise unable to give informed consent, were pregnant or breastfeeding, were allergic to disulfiram or benzodiazepines, had previously experienced delirium or alcohol withdrawal seizures, had multiple or pathological fractures, had an American Society of Anesthesiologist (ASA) score ≥ 4 or fulminant heart or liver insufficiency, if the surgery was cancelled or the patient received external fixation of the fracture.

Study groups

Out of 141 eligible patients, 64 patients gave informed consent to participate in the study. The patients were recruited from Bispebjerg Hospital and Hvidovre Hospital in Denmark between April 2010 and October 2013 and were allocated to GSP-A ($n=32$) or usual care/control ($n=32$). They were stratified for each center and block-randomized in blocks of unknown sizes.

The intervention group began the 6 week GSP-A immediately before or after surgery, consisting of a structured patient education program with weekly meetings (5 in total), including a motivational conversation in the beginning with reflections on benefits and costs of continued drinking vs cessation, and teaching sessions on the damaging effects of alcohol as well as discussions of risk situations and relapse prevention. Further, the intervention group received disulfiram (200 mg x 2 per week) and B-vitamin and Thiamin. The patients in the intervention group also received benzodiazepines if they developed abstinences. The GSP-A is developed based on the gold standard programme for smoking cessation with the same structure and content adapted to alcohol cessation (18). The control group received the orthopedic department's standard care for patients with ankle fracture and hazardous alcohol intake, which include screening all patients with hazardous alcohol intake for abstinence and treatment with benzodiazepines if needed.

All participants were free to seek alcohol treatment outside of the GSP-A. All participants were also informed of smoking as a risk factor for postoperative complications, and recommended to quit smoking, as part of the routine, but it was not further mentioned unless the participant brought it up. Both groups were followed up at 6 weeks. All patients underwent internal fixation and anaesthesia according to the department's routine, including thrombo-embolic and antibiotic prophylaxis.

Registration of lifestyle factors/Outcomes

The lifestyle factors were registered at baseline and at follow-up after 6 weeks and defined as; Smoking: daily smoking, Overweight: BMI > 25 kg/m² and/or waist measurement > 80 cm(W)/94 cm(M). Subjects were weighed and had their waist measured by the investigator with measuring tape. Height was self-reported. Risk of malnutrition: BMI $< 20,5$ kg/m² and/or weight loss during the last 3 months and/or reduced food intake during the last week and/or severe endocrine stress metabolism. Physical inactivity was self-reported as physical activity < 30 min per day during the last month (19,20).

Analyses

Three of the 64 patients were excluded in this analysis. Two patients from the control group were excluded shortly after inclusion because they underwent external fixation. One patient in the GSP-A group withdrew the informed consent on the same day as inclusion, and there was therefore no data on this patient. For patients who dropped out or cancelled their 6-week follow-up, baseline data was used for analyses. The follow-up rate at 6 weeks was 88% in the GSP-A group, and 93% in the control group (see trial profile in figure 1).

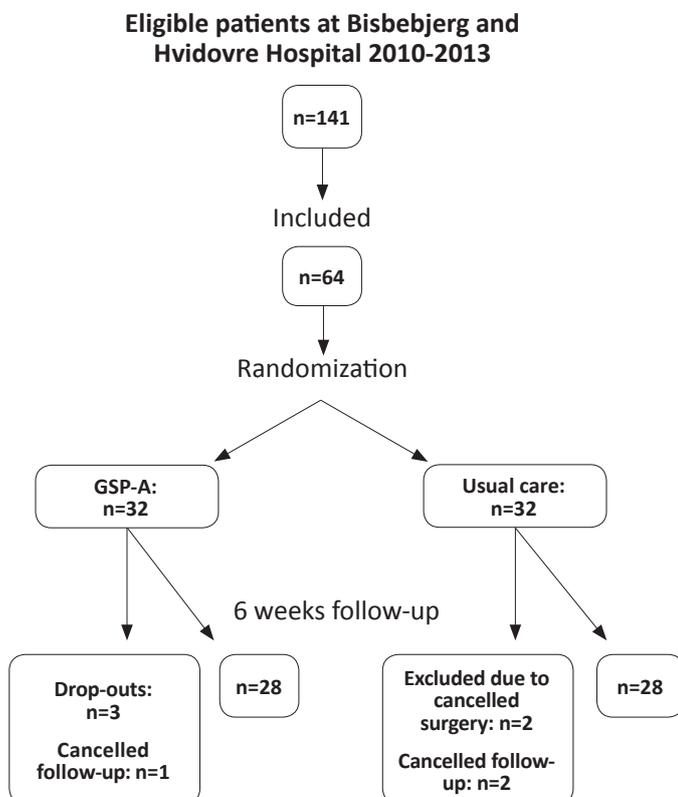
Data were presented as numbers (percentages) and medians (range). The two groups were compared at baseline and follow-up regarding the individual lifestyle factors by intention to treat using non-parametric statistics; Fischer's exact test and Pearson Chi-square. The same method was used to perform the per protocol analyses, which investigated the effect of alcohol abstinence, regardless of study group, on lifestyle risk factors. P-values < 0.05 were considered statistically significant.

A sample size calculation was performed to provide an estimate on how many study subjects would be required to find a 20% decrease in daily smoking with a risk of type 1 error on 5% and a type 2 error of 20% ($n=2825$). The analyses were performed in IBM SPSS v. 19 and Excel 2010.



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Figure 1 Trial profile



Results

Baseline characteristics

Table 1 shows the baseline characteristics for the GSP-A and the control group. There were more men than women in both groups, and the median age was 50 years in the GSP-A group versus 54,5 years in the control group. About one in three in each group were alcohol dependent, and the alcohol consumption in the week before inclusion had a median of 35 and 31 units in the two groups, respectively. Most of the patients were unemployed at the time of inclusion, and had no or short education apart from public school. In the GSP-A group 52% had comorbidity, psychiatric disorders being the most common, followed by lung disease. In the control group 37% had comorbidity and also in this group psychiatric disorder and lung disease were the most common. Most of the patients had an ASA-score of 1 (52% in the GSP-A versus 40% in the control group) or 2 (48% versus 50%, respectively). Regarding lifestyle risk factors there were more daily smokers in the GSP-A group than in the control group (77% vs 50%), and there were also more patients with physical inactivity in the GSP-A group (68% vs 40%). The majority of patients were overweight (77% versus 80%, respectively). There were fewer study participants in risk of malnourishment in the GSP-A group than in the control group (19% vs 33%). In total most of the study partici-

Table 1 Baseline characteristics presented in number (%) or median (means)

	Intervention n=31	Control n=30
Bispebjerg Hospital	18 (58%)	19 (63%)
Age (years)	50 (26-77)	54,5 (20-78)
Gender (men)	21 (68%)	19 (63%)
Alcohol units in the last week	35 (14-106)	31 (2-114)
Alcohol dependency (ICD-10)	11 (35%)	11 (37%)
Missing data	1 (3%)	0 (0%)
Employed	14 (45%)	11 (37%)
Education		
None	7 (23%)	10 (33%)
Short	14 (45%)	9 (30%)
<3 years	1 (3%)	2 (7%)
3-4 years	3 (10%)	5 (17%)
>4 years	5 (16%)	4 (13%)
Missing data	1 (3%)	0 (0%)
Comorbidity		
Patients with comorbidity	16 (52%)	11 (37%)
Lung disease	4 (13%)	2 (7%)
Cardio-vascular disease	6 (19%)	5 (17%)
Diabetes	1 (3%)	0 (0%)
Liver disease	0 (0%)	2 (7%)
Gastrointestinal disease	4 (13%)	2 (7%)
Neurologic disorder	2 (6%)	1 (3%)
Psychiatric disorder	10 (32%)	5 (17%)
Musculoskeletal disorder	2 (6%)	2 (7%)
Other	1 (3%)	3 (10%)
ASA-score*		
1	16 (52%)	12 (40%)
2	15 (48%)	15 (50%)
3	0 (0%)	3 (10%)
Lifestyle risk factor in addition to alcohol		
Daily smoking	24 (77%)	15 (50%)
Risk of malnourishment	6 (19%)	10 (33%)
Overweight	24 (77)	24 (80%)
Physical inactivity	21 (68%)	12 (40%)
Total nr of lifestyle risk factors in addition to alcohol		
1 risk factor	4 (13%)	8 (27%)
2 risk factors	12 (39%)	15 (50%)
3 risk factors	13 (42%)	5 (17%)
4 risk factors	2 (6%)	2 (7%)

*American Society of Anaesthesiologist physical status classification



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pants had 2 or 3 risk factors in addition to hazardous alcohol consumption.

Intention-to-treat analysis

Table 2 shows the results of the ITT-analysis. The results showed no significant differences between groups regarding risk of malnutrition, overweight or physical inactivity after 6 weeks, but a significant difference regarding daily smoking with the GSP-A group having twice as many daily smokers as the control group (84% vs. 43%). However, this difference was also present at baseline (Table 1.) Figure 2a-d illustrates the percentage of patients with a certain risk factor at baseline and at the 6 weeks follow-up.

Table 2 ITT-analysis for lifestyle factors at 6 weeks follow-up

	Intervention n=31	Control n=30	P-value
Daily smoking	26 (84%)	13 (43%)	0.001*
Risk of malnutrition	12 (39%)	12 (40%)	0,92
Overweight	21 (68%)	22 (73%)	0.63
Physical inactivity	25 (81%)	25 (83%)	1

*statistically significant; $p < 0.05$

Per protocol analysis

Alcohol abstainers and non-abstainers after 6 weeks were found to be comparable regarding to baseline characteristics. The results of the per protocol analysis, showed that there were no significant differences between alcohol abstainers and non-abstainers regarding lifestyle risk factors after 6 weeks. The results of this analysis are shown in Table 3. Figure 3a-d illustrates the percentage of patients with a certain risk factor at baseline and at the 6 weeks follow-up.

Table 3 Per protocol-analysis for lifestyle factors at 6 weeks follow-up

	Alcohol abstainers n=22	Non-abstainers n=39	P-value
Daily smoking	15 (68%)	24 (62%)	0.60
Risk of malnutrition	8 (36%)	16 (41%)	0,72
Overweight	17 (77%)	26 (67%)	0.56
Physical inactivity	19 (86%)	31 (79%)	0.73

Discussion

This study showed that intensive alcohol cessation intervention does not induce smoking cessation nor does it affect other non-targeted risk factors, including overweight, risk of malnutrition and physical inactivity in the intervention period following acute fracture surgery. The lack of significant differences between study groups

Figure 2a-d Development of the individual lifestyle risk factors, from inclusion to 6 weeks follow-up, respectively in the GSP-A (full line) and control group (dotted line); intention to treat analysis

Figure 2a)

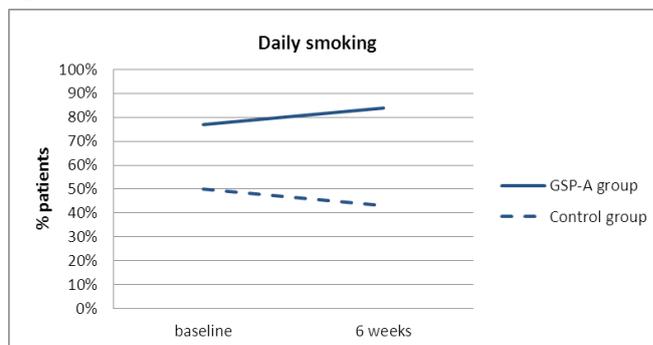


Figure 2b)

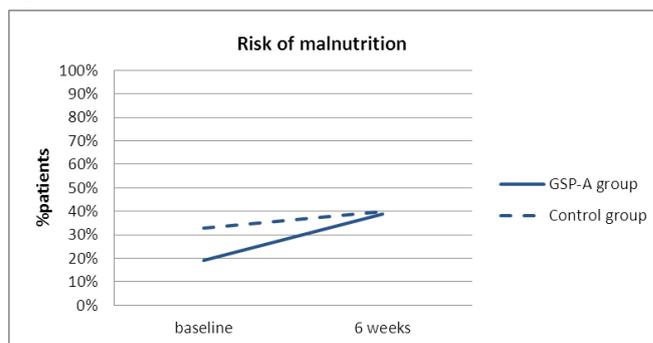


Figure 2c)

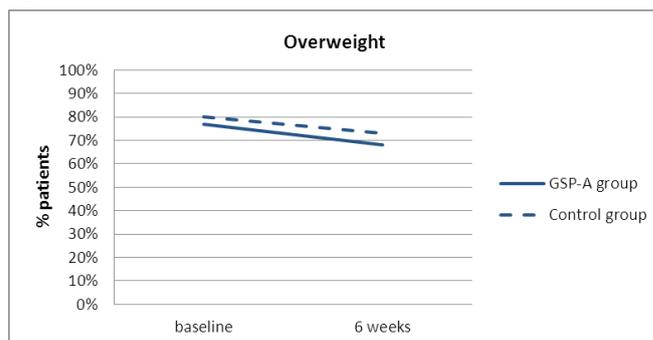
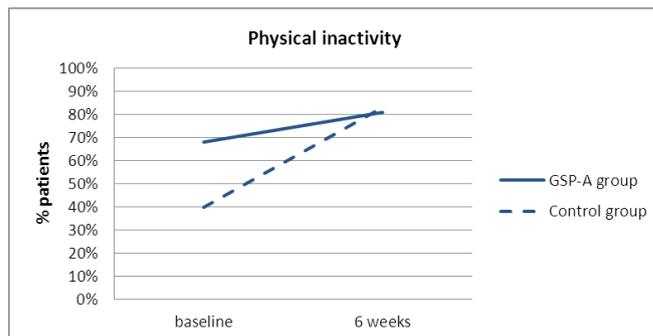


Figure 2d)





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in the ITT-analysis, along with the per protocol analysis, suggests that neither the intensive intervention program nor alcohol cessation in itself affect non-targeted lifestyle factors.

We hypothesized that there would be a general change of lifestyle in the patients who received the alcohol intervention, but our findings are similar to the results from less intensive programs. Brief alcohol interventions have been found not to have an effect on smoking (21) and smoking cessations have been found not to have an effect on alcohol consumption (22). The results from this study, which, to our knowledge, is the first to investigate the effect of an intensive alcohol intervention in a surgical setting on other non-targeted lifestyle factors, together with the above mentioned studies, points in the direction of non-targeted lifestyle factors not being affected by monofactorial lifestyle interventions.

Since alcohol interventions appear not to induce smoking cessation, combined interventions are probably needed. Some might argue that when stopping to drink alcohol it is too difficult also to cease smoking, but recent research has shown that not only are 75% of smokers in alcohol treatment interested in quitting smoking (23), it is definitely possible, and it has been shown that smoking cessation does not hurt sobriety (24-27). Some studies have even shown that smoking cessation is associated with improved alcohol intervention outcome (28).

In general, the participants in this study constituted a very vulnerable group of patients, as one third were addicted to alcohol and the majority were also smokers and overweight. The number of physically inactive and malnourished patients was also high. Overall, this study group has more lifestyle risk factors both in comparison to hospital patients in general and to the background population. The Scand-Ankle study group contained 64% daily smokers compared to around 20% among hospital patients in general (15) and 15-20% in the Danish background population (29;30). Further, there were close to 80% overweight patients in the Scand-Ankle study group compared to 68% of hospital patients in general (15), and a little less than half of the background population (29). In Denmark around 50% of the population does not have any risk factors, 30% have one, and a few have two or more risk factors (31).

The picture presented in the Scand-Ankle study group is completely different. In addition to having high alcohol consumption, a majority of the study subjects had additionally two or three risk factors. This, together with the results that the GSP-A does not contribute to a general

Figure 3a-d shows the development of the individual lifestyle risk factors, from inclusion to 6 weeks follow-up, respectively in alcohol abstainers (full line) and non-abstainers (dotted line); per protocol analysis

Figure 3a)

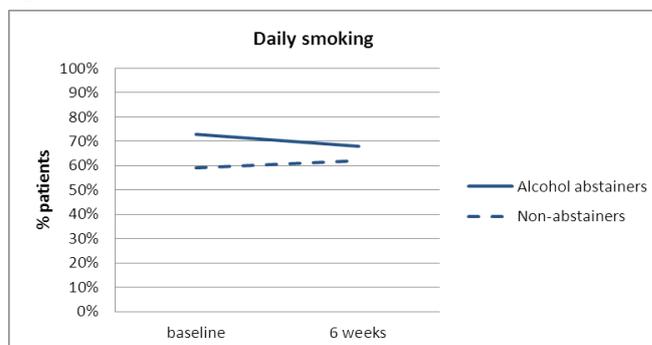


Figure 3b)

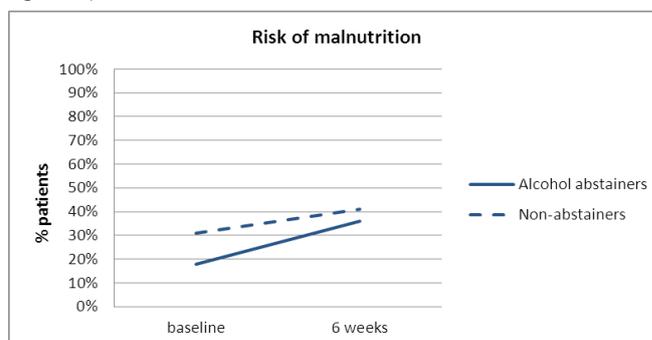


Figure 3c)

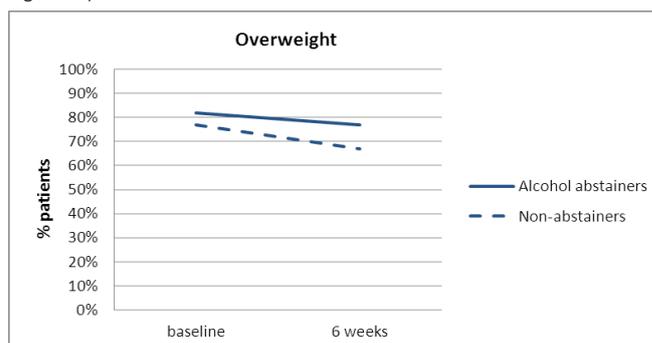
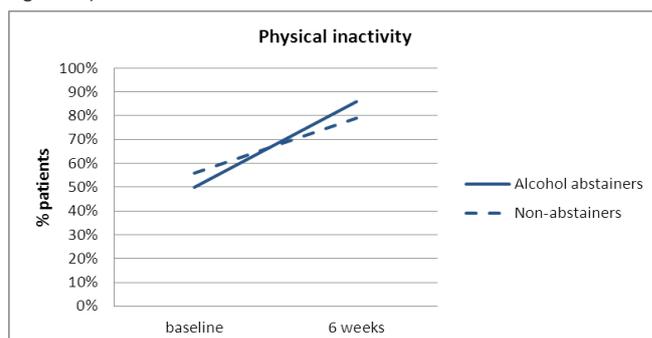


Figure 3d)





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change of lifestyle, call for development and implementation of lifestyle interventions targeting multiple risk factors to achieve a synergetic effect.

Bias and limitations

There is a possibility that there is a difference which we have failed to detect due to the small study sample (Type-2 failure). However, based on our results a new study would require about 2825 patients.

Another bias was that the participants could not be blinded to the group allocation nor could the investigators. This was not possible because of the nature of lifestyle intervention programmes. Height, food intake and physical activity were self-reported and might therefore also be a source of bias.

Conclusion & future perspective

The results of this study showed no effect of the GSP-A on lifestyle risk factors other than alcohol consumption. This suggests that in relation to the Scand-Ankle study, a potential effect on postoperative complications following ankle fracture surgery is related to the GSP-A and its effect on alcohol intake and not a general change of lifestyle.

In regard of smoking, overweight, malnourishment and physical inactivity all being risk factors that increase the risk of developing postoperative complications, it is relevant to further investigate the effect of multiple lifestyle interventions in surgical settings, to achieve the best outcome for the patient.

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Contribution details

Conception and design: HT

Acquisition, analysis and/or interpretation of data: All

Drafting the article: EW

Revising and approving the article: All

Competing interests

None declared

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