

ABSTRACT

We prospectively studied 220 consecutive patients undergoing arthroscopic procedures of the shoulder and the knee in order to assess the efficacy of the VitalWrap System. Our study design was a prospective, non-randomized, unblinded trial which included 220 patients undergoing arthroscopic procedures of the knee and shoulder. In this study, patients were included who are undergoing knee arthroscopy for meniscal tear, chondral injuries or ligamentous tears. Shoulder arthroscopic procedures included decompressive acromioplasty of the shoulder with or without Mumford procedure, arthroscopic debridement of rotator cuff tears or rotator cuff tears undergoing arthroscopic repair or arthroscopic labral procedures including SLAP repairs.

STUDY DESIGN

This non-randomized, unblinded trial included 220 outpatient arthroscopic orthopedic procedures. Postoperatively the patients who underwent arthroscopic procedures of the knee or shoulder were treated with the VitalWrap System and its efficacy was studied. Of the 220 patients, 193 received active treatment with the VitalWrap System with alternating heat and cold therapy during the postoperative period. There were 27 controlled patients who utilized the VitalWrap System with only cold therapy.

Patients treated with the VitalWrap received cold therapy for 8-10 hours per day for the first 3 days post procedure. The cold therapy was set to the minimum setting on the VitalWrap at approximately 40°F. The thermal protocol was then altered beginning on the fourth day to 15 minutes of heating set to the maximum setting on the VitalWrap at 105°F and 45 minutes of cooling set to the minimum setting on the VitalWrap at approximately 40°F in 1 hour period for 3-6 hours per day through the duration of the treatment period.

Patients in the control group were treated with the VitalWrap and received cold therapy for 8-10 hours per day for the first 3 days post procedure. The cold therapy was set to the minimum setting on the VitalWrap at approximately 40°F. This thermal protocol was continued beginning on the fourth day with cooling set to the minimum setting on the VitalWrap at approximately 40°F for 3-6 hours per day through the duration of the treatment period.

The median (range) follow-up for the active treatment group was 14 days (13-14 days), and for the control patients was 8 days

(6-11 days).

The pain scores were recorded for each subject utilizing the visual analog scale (VAS) for 14 consecutive days. Higher scores indicated greater pain. The patients were also asked about the duration of VitalWrap use, number of pain medications and subjective pain relief score on a visual analog scale of 0-10 with 0 being ineffective.

All patients received conventional pain medications in addition to the VitalWrap and were instructed to use the pain medications on an as needed basis.

METHOD

Knee (standard deviation) visual analog scores at baseline at the end of the follow-up were compared between the treatment groups utilizing a paired P-test. The difference in the visual analog score from the baseline to the end of the follow-up was calculated as follow-up VAS-baseline VAS; the difference in the analog scores was also compared within the two groups utilizing an independent P-test. Generalized estimating equations (GEE) were utilized to calculate the mean progression/regression of the pain relief score over the follow-up period accounting for within subject variation. GEE models were then fitted to correlate VAS to duration of VitalWrap use. Subjective pain relief score was also correlated with number of VitalWrap use. P-test was used to compare the mean VAS score according to which treatment was most effective in reducing pain.

RESULTS

Mean VAS score plus/minus standard deviation were not different between the treatment group at baseline with a P = .60. VAS scores were significantly different at the end of the follow-up with P less than .0001. Visual analog score reduced in both of the groups but reduction was significantly greater in the active treatment group when compared to the control with P values less than .0001.

Subjective pain relief score among the active treatment group was significantly increased over time with beta estimates or rates equaling .01 per day with P value equal to .002. This indicated increasing perception of effectiveness of the VitalWrap use with alternate heat and cold therapy. Among the control group there was a decrease in the score with beta estimate or rate - .08 per day with P value of .0001. This indicated an ineffectiveness of the VitalWrap with cold therapy only. The rate change in pain relief score was statistically significant and different between the two groups with P value of .0009.

Duration of VitalWrap use over the follow-up period, the mean plus/minus standard

deviation of the VitalWrap use in the active treatment group was 3.2 +/- .02 hours per day whereas among the control it was noted that the treatment period was 2.3 +/- .12 hours per day. The difference was statistically significant. P-value less than .0001. Longer duration of daily use among the active treatment group did also possibly indicate satisfaction with VitalWrap use in terms of pain reduction.

SUMMARY

In this study, we prospectively studied 220 consecutive patients undergoing arthroscopic procedures of the shoulder and knee. This was in order to assess the efficacy of the VitalWrap System postoperatively. Our study design was a prospective, non-randomized, unblinded trial which included arthroscopic procedures of the shoulder and knee. The shoulder procedures included arthroscopic decompressions, +/- Mumford procedures, with arthroscopic debridement of partial rotator cuff tears, arthroscopic repairs of rotator cuff tears and arthroscopic labral repairs, arthroscopic SLAP repairs, arthroscopic labral debridement. The knee procedures included procedures performed for arthroscopic treatment of meniscal tears, chondral injuries and ligamentous tears. Overall our results did indicate that the subjective pain relief score among the active treatment group was significantly increased over time when compared to the control group. This would preliminarily indicate that utilization of the VitalWrap System postoperatively with an alternating cold with heat treatment may have efficacy in the treatment of patients undergoing shoulder and knee arthroscopic procedures.