Effectiveness of Standard of Care versus Its Combination with Reflexology, and Sham Reflexology on Preoperative Anxiety in Patients Undergoing Laparoscopic Cholecystectomy: A Randomized Controlled Trial. Preliminary Results

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BACKGROUND

- Preoperative anxiety is associated with a negative surgery experience and increased morbidity with implications for public health. Several studies have shown that Reflexology can reduce preoperative anxiety.
- We assessed the effectiveness of standard of care combined with Reflexology or Sham Reflexology, versus standard of care alone, in reducing preoperative anxiety in patients undergoing Laparoscopic Cholecystectomy.

METHODS

- We conducted a single blind randomized controlled trial in Bnai Zion Medical Center in Haifa. The complete study will include approximately 300 patients, in three different arms (100 patients in each): two intervention groups: (1) reflexology and standard of care (SOC); (2) sham reflexology and SOC; and (3) a control group of SOC alone
- Patients were assessed for anxiety using VAS-A (Visual Analogue Scale for Anxiety) questionnaires before (at the surgery department) and at entry to the holding room area. Prior to transfer to the surgery theatre, the same evaluation was repeated.
- Treatment protocol: standard treatment included premedication with anxiolytics (Oxazepam and Diazepam) according to the anesthesiologist's decision. Reflexology and sham reflexology protocols were agreed upon by a group of experts through a Delphi process, and the intervention was applied for 15 minutes by certified therapists.
- P values of 0.014 or less were considered statistically significant. Data were analyzed using SPSS. A Bonferroni test was performed to examine the change in the anxiety level 'before' and 'after' intervention.

RESULTS

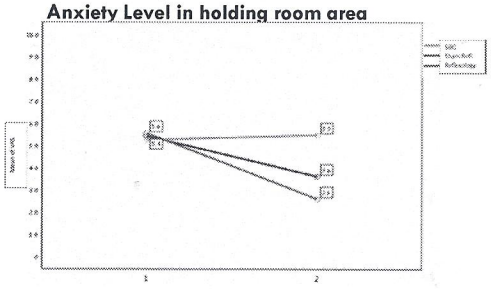
Patient Characteristics

Parameter	SOC n=44	Sham Reflexology n=46	Reflexology n=45	Pvalue
Age	48.5±15.9	52.1±16.5	49.8±14.8	P=0.54
BMI	28.8±5.4	28.4±5.1	26.9±4.5	P=0.22
Gender (female)	29 (65.9%)	30 (65.2%)	27 (60.0%)	P=0.82
Surgery at past	28 (70.0%)	22 (48.9%)	27 (61.4%)	P=0.13
Cardiovascular	11 (26.8%)	14 (31.8%)	16 (36.4%)	P=0.64
Gastroenterologic/hepatobiliary	7 (17.1%)	4 (9.1%)	8 (18.2%)	P=0.43
Renal/Urology	1 (2.4%)	4 (9.1%)	3 (6.8%)	P=0.44
Metabolic/Endocrinologic	24 (58.5%)	24 (54.5%)	22 (50%)	P=0.73
Hemato/Oncologic	2 (4.9%)	2 (4.5%)	5 (11.4%)	P=0.37
Neurologic	-	-	2 (4.5%)	P=0.14
Tomophobia	-	-	-	

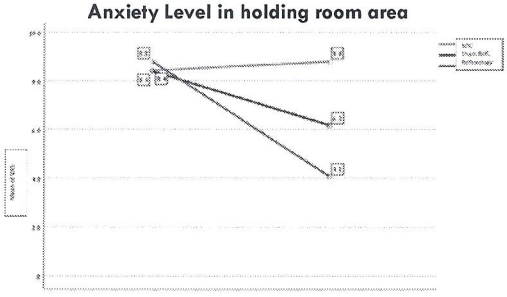
Comparison of mean Anxiety Level between study arms

Anxiety in induction room	Groups	Mean	Std. Deviation	N	Pvalue
Anxiety in induction room (assessment before)	SOC	5.250	2.6774	44	
	Sham Reflexology	5.424	2.4449	46	ns
	Reflex	5.557	2.7623	44	
	Total	5.410	2.6120	134	
Anxiety in induction room (assessment after)	SOC	5.477	2.8160	44	Soc vs. Refl. p<0.001
	Sham Reflexology	**3.598	2.5812	46	Soc vs. Sham Refl. P=0.002
	Reflex	**2.591	2.2652	44	Sham Refl. vs. Refl. P=0.19

Change in Mean VAS Anxiety Level in holding room area



Change in Mean VAS>7 Anxiety Level in holding room area



- 135 patients participated in the study so far. 18% declined to participate.
- Preoperatively, Reflexology (5.5-2.6, p<0.001) and Sham Reflexology (5.4-3.6, p<0.001) treatments were associated with a trend in reduction of baseline anxiety level, but the difference was not clinically or statistically significant (VAS-A=1.00, p=0.19).
- Comparison of mean anxiety score showed significant improvement in the Reflexology arm compared to the SOC arm (p<0.0001), but not as compared to Sham Reflexology. In contrast, severe anxiety (VAS>7) was associated with a significant clinical and statistical difference between the Reflexology and the Sham Reflexology arms (difference VAS-A=2.1, p=0.01).

SUMMARY & CONCLUSIONS

- **This interim analysis on 135 out of 300 patients planned in the study has shown that Reflexology treatments combined with SOC reduce severe preoperative anxiety significantly, compared to Sham Reflexology and standard treatment alone.**
- **In light of the scope of preoperative anxiety and its implications for public health, the combination of Reflexology therapy with SOC should be considered for reducing preoperative anxiety.**