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Promoting a Patient Centered Approach in Clinics by Using a Different Way to Present Data of an Intervention Study: Some Examples from North India

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Abstract

The ultimate objective of any research in medical field is to benefit the patients. Therefore, it is important to present the study findings in a way to facilitate adoption of patient centered approach in OPDs. Most of the research data published on interventional studies shows the change in mean scores and reflects overall group wise impact. There is less focus on the effect of an intervention on symptom wise changes in the health of status of individual patients. The objective of this article is to suggest a different way for summarizing results of few intervention studies including that of the authors. Data from three Indian studies was taken. These studies have tabulated category wise result of shift in the symptom status of individual patients. In one of the study, 3 cases of moderate severity remained so in the same category even after intervention. Similarly, 20 mild cases remained mild and 1 severe case remained severe and so on. In this method of tabulating raw data, each case is entered in one cell only. Such an information is not reflected in the data format used in Tables where no inference can be drawn regarding the patients who did or didn't respond to the intervention, e.g., their profile, compliance level etc. In nutshell, what worked and what did not work for the patients can be found out.

Keywords: Patient centered approach; Data presentation; Intervention studies

Introduction

The ultimate objective of any research in medical field is to benefit the patients [1]. In modern scientific era bulk of the patient care related decisions are taken after evidence based research where RCTs and meta-analysis top the grade [2]. Therefore, it is important to present the study findings in a way to facilitate adoption of patient centered approach in OPDs.

Over last 20-30 years there have been many efforts to ensure standardized uniform reporting of clinical trials data e.g., Consolidated Standards of Reporting Trials (CONSORT) Statement, PRISMA [3]. However, no specific recommendations are there for presenting the data.

By and large, the quantitative research is expressed in numbers and statistics. Data presentation can facilitate or hamper its comprehension. While reporting the results an attempt should be made to try out the data presentation in different ways. Adequate care must be taken to choose the best way of presentation. Most of the research data published on interventional studies shows the change in mean scores and symptoms score test from baseline to end line for intervention and control arms. Intra and inter group comparisons are done. But such data reflects overall group wise impact. There is less focus on the effect of an intervention on symptom wise changes in the health of status of individual patients. The objective of this article is to suggest a different way for summarizing results of few intervention studies including that of the authors.

Methods

The first author (MS) completed an intervention study (2012-2015) for comparative effect of non-pharmacological interventions on the pain of patients suffering from Knee osteoarthritis (KOA) (CTRI/2014/01/004270) [4]. In the intervention study, eligible KOA patients (N=123) were divided into two groups for the RCT. The patients aged 40-65 years of either gender without significant deformity or co-morbidities needing surgery (e.g., meniscus tears etc.) were enrolled. The Western Ontario and McMaster Universities Osteoarthritis Index, visual analogue scale (VAS), performance based tools were used for the assessment of patients before and after intervention.

The intervention package included counseling on exercises, weight reduction, pain coping strategies viz.; meditation, kinesthesia, balance and agility exercises. The customization of the set of exercises for each patient was done in consultation with Orthopedics surgeon and physiotherapist. There were total scheduled 26 visits over a period of 12 months. Supervised sessions were held in the intervention room. Return demonstration were taken on every follow up visit and corrections were advised to patients. Patients were advised to perform exercises at home and maintain logbook also. There were many drop outs in the study as many patients avoided physical presence on the follow up visits and preferred to contact the researcher on what's app, Skype and email.

Percentage, mean, standard deviation, paired t-test for evaluating the difference in mean scores of the outcome variables was conducted. In addition to that, symptom wise quantification in terms of patients benefiting from the respective intervention was also done. Clearance for conducting the trial was obtained from the institute ethics committee. Written informed consent was sought from the patients. In case of illiterate patients the consent was taken from caregivers.

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Besides her results data on similar way of data presentation was also gathered from work done in North India. Tables from the collected studies are also presented here.

Rashmi et al. conducted a study to ascertain the effect of a customized intervention package on the change in signs and symptoms of pelvic organ prolapse (POP) (CTRI/2010/091/001190) [5]. The patients were randomized in group A and group B. POP Symptom Scale Score (POP-ss) was used for the assessment. Patients enrolled in group A were personally trained on Kegel exercises, life style modifications. But only self-instruction manual was given to group B patients. Thereafter, follow up was done to know the effect of the assigned intervention(s) on the change in symptoms of POP for both the groups.

Mehnaz et al. conducted a trial on the Iron, Folate and Vitamin C Supplementation on the prevalence of iron deficiency anemia in non-pregnant females of peri urban areas of Aligarh [6]. In this study, all the non-pregnant females of the age group of 15-55 years formed the reference population, of whom 177 females were randomly selected. Both the control and experimental groups were followed for a period of 100 days. The haemoglobin measurements done at the start of the study at 30 days and at 100 days of supplementation. Ethical aspects were duly addressed in all these studies.

Results

Study 1

POP: Results from Rashmi et al. study wise shown in Tables 1-4. Table 1 represents the improvement in mean POP signs and symptoms score test from baseline to week 24 for both the groups. A group fared better than group B.

Table 2 shows that the absolute percentage point decrease was more in women of group A, e.g., for the symptom 'feeling of something coming down from or in vagina' for group A the decrease was from 73% at baseline to 43.2% at week 24 i.e., 29.8%. However, for group B it was from 76% to only 64.1% i.e., decrease by 11.9%. This signified more women benefited from personal exercise training in group A as compared to those in group B.

In the same study, the severity of symptoms was also assessed by using visual analog scale (VAS). Grading of severity was done into mild, moderate, severe. The change in mean VAS score showing signification reduction at follow up visits with respect to baseline VAS score in group A. This is presented in Table 3 as a new way of data presentation.

Table 4 yields a clear picture about the individual level shift in the severity of POP. For example, it shows that before the intervention there were 6 cases in the severe category. After intervention 3 patients remained in this category. Similarly, from 18 cases of moderate category in the beginning it reduced to 3 cases at the last follow up. Simultaneously, mild cases increased from 30 to 35. Symptom less patients increased from 20 to 33. This indicated a shift from moderate and severe cases to mild or no symptoms. This way of presentation signified the positive impact of personal exercise training on reducing the severity of POP.

Study 2

Anaemia Results from Mehnaz et al. study wise shown in Tables 5 and 6. Table 5 shows that after intervention cases of mild anemia increased from 26 to 51, while that of moderate and severe anemia decreased from 126 to 63 and 23 to 18 respectively. Forty three women attained normal range of hemoglobin after the intervention.

The iron/folate supplementation given daily in sub group 1 brought about significant change ($p<0.05$) in the mean haemoglobin level both at 30 days and 100 days, the improvement being 0.94 g/dl and 2.72 g/dl respectively. In sub group 2 vitamin C supplementation along with iron/folate supplementation also brought significant improvement ($p<0.05$) at 30 days (1.6 g/dl) and 100 days (4.36 g/dl). In the control group where no supplementation was 0.23 g/dl at 30 days and 0.10 g% dl at 100 days, which was found to be insignificant ($p>0.05$).

Study 3

KOA: Results from Sharma et al. study are shown in Tables 7 and 8. Table 7 shows results of the study done by researcher (MS) and depicts that there was a significant improvement in VAS scores in group A at each time period.

The interpretation of shift in severity wise grading shows that at baseline 4 patients were enrolled initially in the 9-10 category of VAS score (Table 8). Within 1 week only 2 patients remained in this category. After 3 months all patients shifted from 9-10 categories to less severe categories. This persisted till 12 months. In the 5-8 VAS score category 25 patients were registered at the baseline. This reduced to 4, 2 and 2 at 3 months, 6 months and 12 months respectively.

Discussion

In Rashmi et al. study the reduction in mean PoPs (Table 1) from baseline to week 24 was significantly more in group A ($p=0.05$). This showed that personal training in group A was more effective in relieving symptoms as compared to self-instruction manual. But the data did not convey about relief obtained in individual symptoms. However, to elaborate the effect of an intervention, symptom wise quantification in terms of women benefiting from the respective intervention(s) also becomes important. This was included in Table 2 data. It showed symptom wise improvement but for the group as a whole for example 73% women reported relief in symptom, "feeling of something coming out of vagina". But it gives no idea about what happened in the remaining 27% cases.

Table 2 also didn't reveal anything about change in the status of individual case. Very often, in presenting results of RCTs, Tables just clearly represent the overall shift or change from baseline to the end of follow up visits. Even from Table 3 the change in severity of VAS as per grading of individual case couldn't be interpreted. This only gave mean score reduction for the group as a whole.

In the Table 4, category wise result of shift in the symptom status of individual patients is shown. For example, 3 cases of moderate severity remained so in the same category even after intervention (see cell no. 6). Similarly, 20 mild cases remained mild and 1 severe case remained severe and so on (cell no. 1 and 11 respectively). Cell no. 7 shows that 2 cases were worsened from 'moderate' to 'severe'. In this method of tabulating raw data, each case will be entered in one cell only. For example, a moderate case who got complete relief will be entered in cell no. 8 only (here 3 such cases were reported).

Such an information is not reflected in the data format used in Tables 1-3 where no inference can be drawn regarding the patients who did or didn't respond to the intervention, e.g., their profile, compliance level etc. However, from Table 4 details of the patients can be found out by tracing back the data. Accordingly evaluation can be done for the reasons for lack of relief in a particular patient. This will help in customization of therapy for bringing improvement in the symptoms.

For example, after tabulating the data as shown in Table 4 we can

Time / Group	Mean POP-ss						
	Baseline	Week 1	Week 3	Week 6	Week 12	Week 18	Week 24
A	5.78	5.62	4.74	3.72	3.43	3.11	2.93
B	7.45	-	-	6.62	-	6.18	6.15

Table 1: Mean POP-ss at baseline and follow up visits in group A and group B.

Prolapse symptoms	Group	Time period						
		Baseline	1 week	3 weeks	6 weeks	12 weeks	18 weeks	24 weeks
Feeling of something coming down from or in vagina	A	73.0	73.0	71.6	70.3	57.2	48.6	43.2
	B	76.0	-	-	73.1	-	69.2	64.1
Uncomfortable feeling or pain in vagina which is worse when standing	A	45.9	45.9	47.3	43.2	28.4	28.4	27.0
	B	57.6	-	-	51.5	-	47.0	42.4
Heaviness or dragging feeling in lower abdomen	A	56.8	56.8	47.3	44.6	31.1	31.1	25.7
	B	66.7	-	-	59.1	-	54.5	51.5
Heaviness or dragging feeling in lower back	A	43.2	43.2	39.3	33.8	20.3	20.3	18.9
	B	50.0	-	-	43.9	-	42.4	42.4
Need to strain (push) to empty bladder	A	21.6	21.6	13.5	8.1	1.4	1.4	1.4
	B	28.8	-	-	28.8	-	27.3	25.8
Feeling that bladder has not emptied completely	A	32.4	32.4	27.0	9.5	6.8	5.4	4.1
	B	39.4	-	-	37.9	-	33.3	33.3
Feeling that bowel has not emptied completely	A	16.2	16.2	8.1	2.7	1.4	1.4	1.4
	B	19.7	-	-	13.6	-	10.6	10.6

Table 2: Percentage of women reporting prolapse symptom present during baseline and follow up visits in group A (n=74) and B (n=66).

Time period	Change in mean VAS score	SD	Z	Wilcoxon Signed Rank Test p value
1 week-baseline	-1.00	5.79	-1.46	0.144
3 weeks-baseline	-5.73	8.30	-5.47	<0.001
6 weeks-baseline	-8.65	10.56	-5.85	<0.001
12 weeks-baseline	-5.73	8.30	-5.91	<0.001
18 weeks-baseline	-11.95	14.03	-5.91	<0.001
24 weeks-baseline	-14.09	16.13	-5.92	<0.001

Table 3: Change in the mean VAS score at follow up visits in group A.

Before \ After	Severity of pelvic organ prolapsed				
	Mild	Moderate	Severe	No symptoms	Total
Mild	[1] 20	[2] 0	[3] 0	[4] 10	30
Moderate	[5] 10	[6] 3	[7] 2	[8] 3	18
Severe	[9] 5	[10] 0	[11] 1	[12] 0	**6**
No symptoms	[13] 0	[14] 0	[15] 0	[16] 20	20
Total	35	3	**3**	33	74

Table 4: Shift in category/severity of pelvic organ prolapse (according to VAS score) in group A before and after intervention i.e., at 24 weeks (n=74).

go back to raw data in case files to compare the profile of 20 'mild' cases (cell-1) who remained 'mild' after intervention with that of 10 cases (cell 4) who became symptomless after intervention. In nutshell, what worked and what did not work for the patients can be found out. Similarly, in the Mehnaz et al. study, the profile of 14 patients who had severe anemia before intervention and continued to remain in the same category after the intervention can be evaluated after getting back to raw data.

As a clinician, the focus needs to be on the cure of the patient and ultimate welfare of an individual patient. Statistical jargon i.e., means, change in the group score don't yield any information which can be used to provide relief to the individual patient. In this context the new way of presenting the data elaborated in the current study can be used to find out the reasons for inadequate response to the therapy.

Conventional data presentation advocates for a particular regime in general for the whole group, i.e., the patients. But the individual factors also affect the results of the treatment given e.g., degree of compliance; presence of co-morbidity etc. New way of data presentation may help us in pinpointing the factors that affect the impact of intervention. Such a comparison of responder's vs non responders will help us in giving tips to the clinician in OPD for optimal patient management.

In the researcher's (MS) study, the case files of individual patients who didn't benefit from the intervention was retrieved and studied. It was observed that 1 patient (age 45 years, female, BMI>30) who remained in 9-10 category after one week was obese. Other patient (age 51 years, female, BMI 25.6) was not fully compliant to the instructions given by researcher. This patient was not interested in doing exercises as reported by her that she didn't feel like to doing exercises all by herself

		After interventions (N=132)				
		Normal	**Mild**	**Moderate**	**Severe**	**Total**
Before Intervention (N=175)	Mild	10	13	01	02	26 (14.8%)
	Moderate	31	35	58	02	126(72%)
	Severe	02	03	04	14	23(13%)
	Total	43 (24.57%)	51 (29.14%)	63 (36%)	18 (10.28%)	175

Table 5: Shift in the severity wise prevalence of anemia before and after intervention.

	Mean 0th day Hb (gm%)	**Mean 30th day Hb (gm%)**	**Mean increase after 30 days (gm%)**	**Mean Hb (gm%) after 100 days**	**Mean increase after 100 days (gm%)**
Controls	8.33	8.40	0.23	8.43	0.10
Cases (sub group 1)	8.30	9.24	0.94	11.02	2.72
Cases (sub group 2)	8.70	10.30	1.6	13.06	4.36

Table 6: Increase in Mean Haemoglobin of the Study Population at the Start and end of the study.

Time period	**Group A**	
	Mean Difference	**n (p value)***
Baseline-1 week	0.854	48 (0.001)
Baseline-3 months	2.20	29 (0.000)
Baseline-6 months	3.0	29 (0.000)
Baseline-12 months	3.6	30 (0.000)

*Wilcoxon Signed Rank sum Test

Table 7: Change in mean VAS score at follow up visits in group A.

VAS Score									
Just after 1 week of intervention phase was over					**3 months**				
After / Before	**0-4**	**05-Aug**	**09-Oct**	**Total**	**After / Before**	**0-4**	**05-Aug**	**09-Oct**	**Total**
0-4	19	0	0	19	0-4	11	0	0	11
05-Aug	12	13	0	25	05-Aug	13	2	0	15
09-Oct	1	1	2	4	09-Oct	1	2	0	3
Total	32	14	2	48	Total	25	4	0	29*
6 months					**12 months**				
After / Before	**0-4**	**05-Aug**	**09-Oct**	**Total**	**After / Before**	**0-4**	**05-Aug**	**09-Oct**	**Total**
0-4	12	0	0	12	0-4	11	1**	0	12
05-Aug	13	1	0	14	05Aug	15	0	0	15
09-Oct	2	1	0	3	09-Oct	2	1	0	3
Total	27	2	0	29	Total	28	2	0	30**

Table 8: Proposed way of data presentation to depict shift in severity as per VAS score in group A (n=63) patients at various duration after intervention.

"*Koi karwan wala bhi chahida"* (Someone should be there to help me to do exercises every day). Accordingly, customization for both patients was done and specific interventions were provided to them for bringing improvement in their condition. Dietary counseling was done for the obese patient. For the second patient involvement of spouse was done for improving adherence to exercise therapy.

Table 7 showed that result of the intervention package had resulted in the reduction of pain after a week as p value (0.001) was significant. But this Table didn't depict anything about individual health status. It yielded only mean score reduction. As a contrast Table 8 depicted details of individual patients as per their response to therapy. It facilitates customization of intervention package for individual.

Hence this way of representing the data clearly depicts symptom wise changes in the health of status of a patient which is not visible through routine way of reporting of the effect of intervention.

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