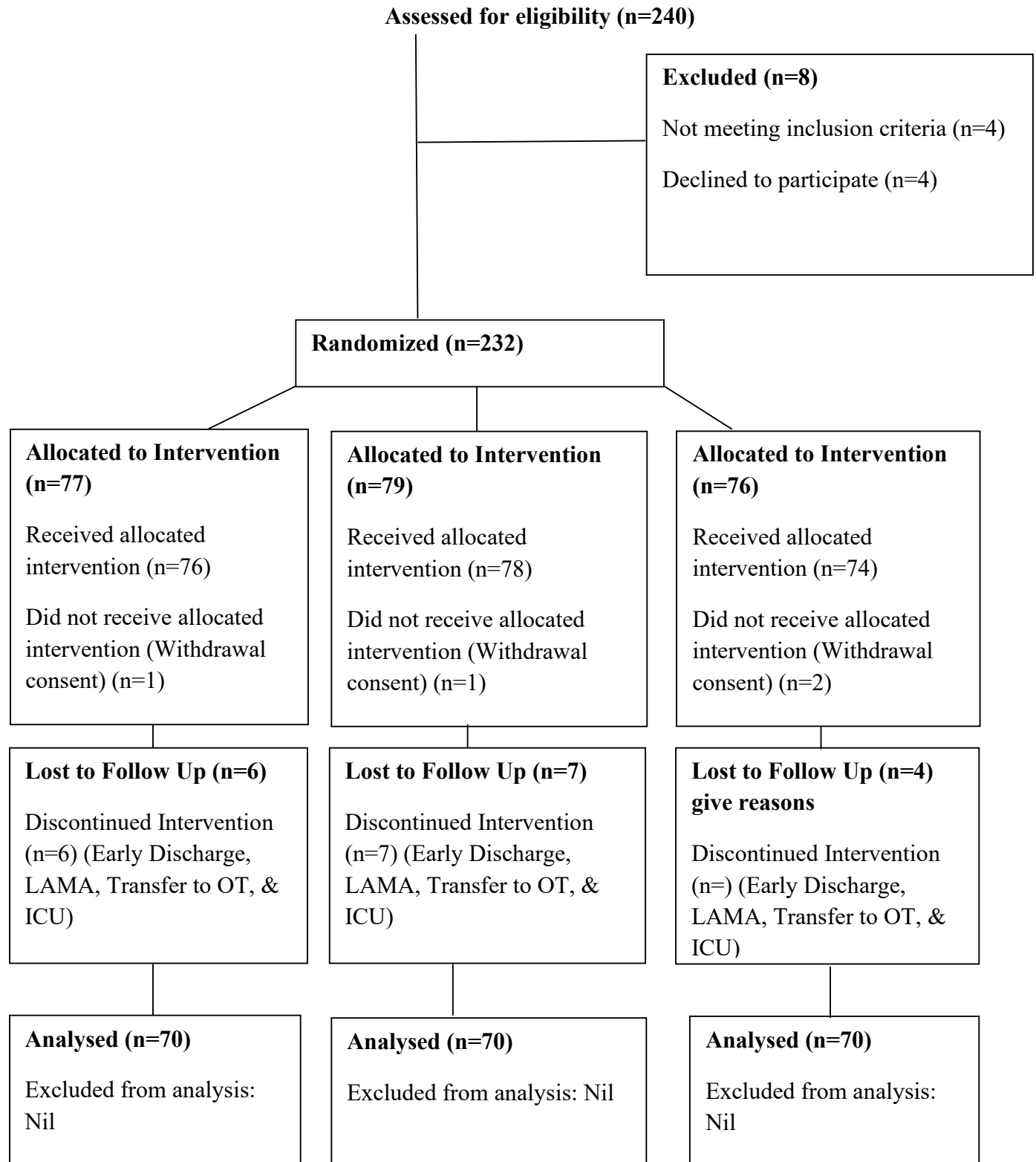


## Participant Flow chart



## RESULTS

### 1. Baseline Characteristics

**Table No.1: Reporting Baseline Demographic and Clinical characteristics**

| Demographic variables |                      | Group         |        |           |        |         |        | Chi square test           |
|-----------------------|----------------------|---------------|--------|-----------|--------|---------|--------|---------------------------|
|                       |                      | Aloe vera gel |        | Olive Oil |        | Control |        |                           |
|                       |                      | n             | %      | n         | %      | n       | %      |                           |
| AGE                   | Less than 30         | 13            | 18.57% | 22        | 31.43% | 12      | 17.14% | $\chi^2=10.30$ p=0.24(NS) |
|                       | 31-40yrs             | 16            | 22.86% | 11        | 15.71% | 20      | 28.57% |                           |
|                       | 41-50yrs             | 15            | 21.43% | 11        | 15.71% | 14      | 20.00% |                           |
|                       | 51-60yrs             | 10            | 14.29% | 9         | 12.86% | 4       | 5.71%  |                           |
|                       | More than 60 yrs     | 16            | 22.86% | 17        | 24.29% | 20      | 28.57% |                           |
| GENDER                | Male                 | 52            | 74.29% | 51        | 72.86% | 50      | 71.43% | $\chi^2=0.14$ p=0.93(NS)  |
|                       | Female               | 18            | 25.71% | 19        | 27.14% | 20      | 28.57% |                           |
| HABITS                | Smoking              | 11            | 15.71% | 8         | 11.43% | 8       | 11.43% | $\chi^2=8.99$ p=0.34(NS)  |
|                       | Alcoholism           | 9             | 12.86% | 3         | 4.29%  | 9       | 12.86% |                           |
|                       | Smoking & Alcoholism | 8             | 11.43% | 5         | 7.14%  | 3       | 4.29%  |                           |
|                       | Tobacco using        | 3             | 4.29%  | 2         | 2.86%  | 4       | 5.71%  |                           |
|                       | None                 | 39            | 55.71% | 52        | 74.29% | 46      | 65.71% |                           |
| BODY BUILT            | Ectomorph            | 57            | 81.43% | 53        | 75.71% | 47      | 67.14% | $\chi^2=3.83$ p=0.15(NS)  |
|                       | Endomorph            | 13            | 18.57% | 17        | 24.29% | 23      | 32.86% |                           |
|                       | Mesomorph            | 0             | 0.00%  | 0         | 0.00%  | 0       | 0.00%  |                           |

The above Table 1 below displayed the demographic information of bed ridden patients those who are participated for the following study on “A quazi experimental study to assess the effectiveness of aloe vera gel versus olive oil in the prevention of pressure ulcers among

bedridden patients in selected hospitals”. Similarity of demographic variables distribution between experimental and control group was assessed using chi square test at p value < 0.05

In the study result, the age distribution among groups varied. The control group had the highest percentage (28.5%) of participants aged over 60, followed by the Olive Oil (24.29%) and Aloe Vera (22.86%) groups, indicating a predominance of older adults, especially in the Control Group. Subjects were predominantly male (72.85%).

The study also documented the personal habits of the subjects. Notably, 11.43% of individuals in the Aloe Vera group reported both smoking and alcohol consumption habits. In comparison, 12.86% of the Aloevera & Control group indicated alcohol consumption, while 15.71% reported smoking as their sole habit within that group. Additionally, in the Olive Oil group, 11.43% of subjects had a smoking habit, with the Control group showing a similar prevalence. The majority of subjects had an ectomorphic body type, accounting for 74.76% of the study population.

**Table 2: CLINICAL VARIABLES AMONG STUDY GROUPS.**

| Clinical variables |                           | Group         |        |           |        |         |        | Chi square test             |
|--------------------|---------------------------|---------------|--------|-----------|--------|---------|--------|-----------------------------|
|                    |                           | Aloe vera gel |        | Olive Oil |        | Control |        |                             |
|                    |                           | n             | %      | n         | %      | n       | %      |                             |
| CO-MORBIDITY       | Diabetes                  | 7             | 10.00% | 6         | 8.57%  | 5       | 7.14%  | $\chi^2=3.92$<br>p=0.86(NS) |
|                    | Hypertension              | 10            | 14.29% | 6         | 8.57%  | 7       | 10.00% |                             |
|                    | Diabetes and Hypertension | 8             | 11.43% | 5         | 7.14%  | 6       | 8.57%  |                             |
|                    | Others                    | 0             | 0.00%  | 0         | 0.00%  | 0       | 0.00%  |                             |
|                    | Nil                       | 45            | 64.29% | 53        | 75.71% | 52      | 74.29% |                             |
| ELEVATION OF BED   | Completely flat           | 16            | 22.86% | 18        | 25.71% | 21      | 30.00% | $\chi^2=7.42$<br>p=0.49(NS) |
|                    | 15                        | 24            | 34.29% | 33        | 47.14% | 20      | 28.57% |                             |
|                    | 30                        | 24            | 34.29% | 16        | 22.86% | 24      | 34.29% |                             |
|                    | 45                        | 5             | 7.14%  | 2         | 2.86%  | 4       | 5.71%  |                             |

|                               |                             |    |        |    |        |    |        |                             |
|-------------------------------|-----------------------------|----|--------|----|--------|----|--------|-----------------------------|
|                               | 60                          | 1  | 1.43%  | 1  | 1.43%  | 1  | 1.43%  |                             |
| <b>INCONTINENCE</b>           | Urinary incontinence        | 5  | 7.14%  | 6  | 8.57%  | 12 | 17.14% | $\chi^2=4.20$<br>p=0.12(NS) |
|                               | Fecal incontinence          | 0  | 0.00%  | 0  | 0.00%  | 0  | 0.00%  |                             |
|                               | Both                        | 0  | 0.00%  | 0  | 0.00%  | 0  | 0.00%  |                             |
|                               | None                        | 65 | 92.86% | 64 | 91.43% | 58 | 82.86% |                             |
| <b>MOBILITY</b>               | Completely limited          | 36 | 51.43% | 27 | 38.57% | 37 | 52.86% | $\chi^2=9.52$<br>p=0.15(NS) |
|                               | Very limited                | 29 | 41.43% | 39 | 55.71% | 31 | 44.29% |                             |
|                               | Slightly limited            | 5  | 7.14%  | 2  | 2.86%  | 2  | 2.86%  |                             |
|                               | No limitation               | 0  | 0.00%  | 2  | 2.86%  | 0  | 0.00%  |                             |
| <b>LEVEL OF CONSCIOUSNESS</b> | Conscious ( GCS : 12-15)    | 63 | 90.00% | 61 | 87.14% | 63 | 90.00% | $\chi^2=0.39$<br>p=0.82(NS) |
|                               | Semi conscious( GCS : 8-11) | 7  | 10.00% | 9  | 12.86% | 7  | 10.00% |                             |
|                               | Unconscious ( GCS : 3-7)    | 0  | 0.00%  | 0  | 0.00%  | 0  | 0.00%  |                             |
| <b>SKIN TURGOR</b>            | Good                        | 43 | 61.43% | 42 | 60.00% | 34 | 48.57% | $\chi^2=6.10$<br>p=0.19(NS) |
|                               | Fair                        | 25 | 35.71% | 28 | 40.00% | 32 | 45.72% |                             |
|                               | Poor                        | 2  | 2.86%  | 0  | 0.00%  | 4  | 5.71%  |                             |
| <b>TREATMENT MODALITY</b>     | Medical                     | 20 | 28.57% | 23 | 32.86% | 22 | 31.43% | $\chi^2=3.91$<br>p=0.42(NS) |
|                               | Surgical                    | 46 | 65.71% | 46 | 65.71% | 42 | 60.00% |                             |
|                               | Rehabilitation              | 4  | 5.71%  | 1  | 1.43%  | 6  | 8.57%  |                             |

In the above table 2 depicted the distribution of clinical variables among bedridden patients in three groups: Aloe vera, Olive oil, and Control. Among the findings, the Aloevera group had 10% with Diabetes, 14.29% with Hypertension, and 11.43% with both conditions. The Olive oil

group had slightly lower rates, with 8.5% having Diabetes, 8.5% having Hypertension, and 7.14% having both. In the Control group, 7.14% had Diabetes, 10% had Hypertension, and 8.57% had both. Bed elevation choices were distributed with 22.8% flat beds in Aloevera, 25.7% in Olive oil, and 30% in Control. 15-degree elevation had 34.2% in Aloevera, 47.14% in Olive oil, and 28.5% in Control. 30-degree elevation had 34.2% in both Aloevera and Control. Urinary Incontinence was reported by 17.1% in Control, 8.5% in Olive oil, and 7.1% in Aloevera. In terms of mobility, Aloe vera had 51.4% completely limited, Olive oil had 38.5%, and Control had 52.5%. Very limited mobility was observed in 41.43% of Aloe vera, 55.71% of Olive oil, and 44.29% of Control. A small percentage had slightly limited mobility. Most participants were conscious, with 90% in Aloe vera, 87.1% in Olive oil, and 90% in Control, while fewer were semi-conscious. Good skin turgor was observed in 61.43% of Aloe vera, 60% of Olive oil, and 48.5% of Control, while fair skin turgor was seen in 35.71% of Aloe vera, 40% of Olive oil, and 45.72% of Control. Poor skin turgor was rare, with 2.86% in Aloe vera and 5.71% in Control. Treatment modalities included medical treatment for 28.5% in Aloe vera, 32.8% in Olive oil, and 31.43% in Control, surgical treatment for 65.7% in both Aloe vera and Olive oil, and 60% in Control, and rehabilitation for 5.7% in Aloe vera, 1.43% in Olive oil, and 8.57% in Control.

## Outcome Measures

**Table 3: Multiple comparison of pretest, posttest level of risk scores between experimental and control group.**

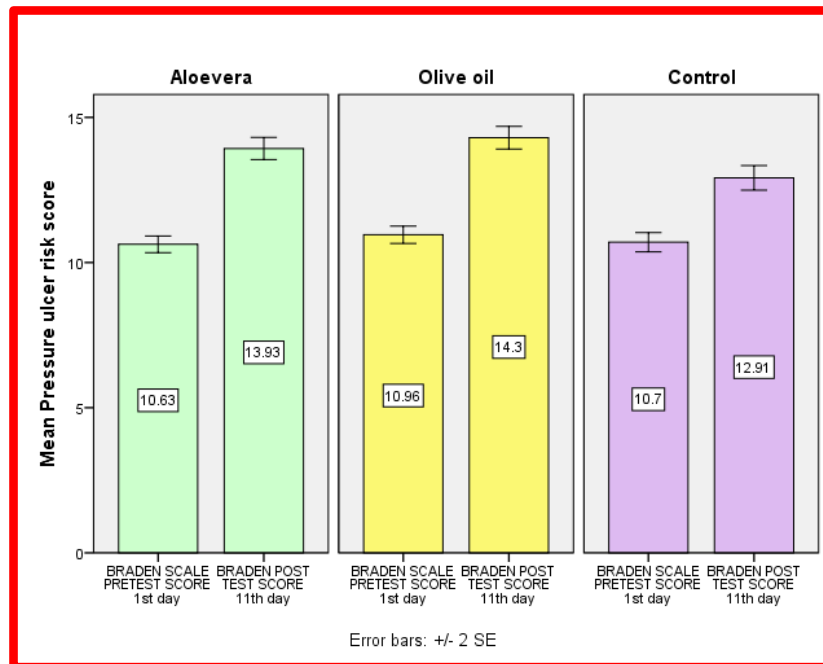
| Domains  | Assessment | Experimental group |      | Oneway ANOVA F-test score |                | Bonferroni t- test  |      |         |
|----------|------------|--------------------|------|---------------------------|----------------|---------------------|------|---------|
|          |            | Mean               | SD   | F value                   | P value        | Comparison          | MD   | P value |
| Pretest  | Aloevera   | 10.63              | 1.21 | F=1.27                    | p=0.28(NS)     | Aloevera vs Olive   | 0.33 | 0.39    |
|          | Olive oil  | 10.96              | 1.24 |                           |                | Aloevera vs Control | 0.07 | 0.93    |
|          | Control    | 10.70              | 1.39 |                           |                | Olive vs Control    | 0.26 | 0.71    |
| Posttest | Aloevera   | 13.93              | 1.60 | F=12.87                   | p=0.001*** (S) | Aloevera vs Olive   | 0.37 | 0.57    |
|          | Olive oil  | 14.30              | 1.64 |                           |                | Aloevera vs Control | 1.02 | 0.001   |
|          | Control    | 12.91              | 1.78 |                           |                | Olive vs Control    | 1.39 | 0.001   |

**MD= mean difference \*\*\*  $P \leq 0.001$  very high significant DF= degrees of Freedom**

**In pretest, Oneway ANOVA F- test** shows that mean risk score difference is statistically not significant between aloe vera gel group, olive oil group and control group ( $F = 1.27, p > 0.05$ ). Post hoc multiple comparisons of Bonferroni t- test p-values, shows aloe vera vs Olive (0.39), aloe vera vs control (0.93) and Olive Vs Control (0.71) are not significant.

**In posttest, Oneway ANOVA F- test** shows that mean risk score difference is statistically significant between aloe vera gel group, olive oil group and control group ( $F = 1.27, p > 0.05$ ). Post hoc multiple comparison of Bonferroni t- test p-values, shows aloe vera vs Olive(0.57) not significant but aloe vera vs control(0.001) and olive Vs Control(0.001) are significant. So we can conclude , there is no significant difference between aloe vera group and olive group risk

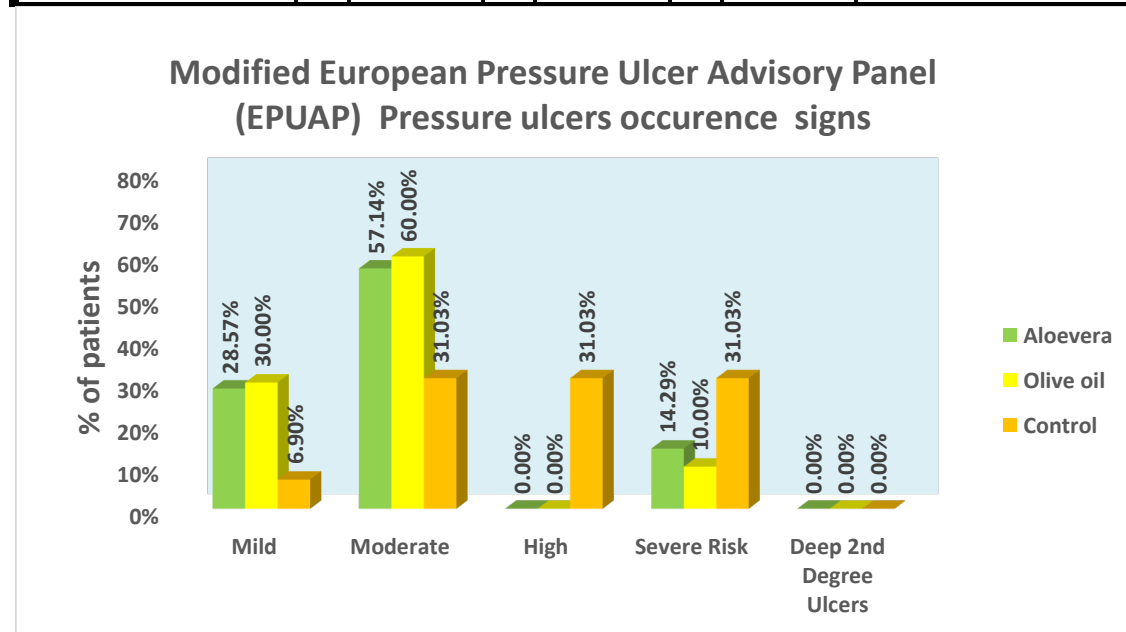
score but when comparing with control both groups are significantly different from control group risk score.



**FIGURE 1: COMPARES THE PRESSURE ULCER LEVEL OF RISK SCORE BETWEEN EXPERIMENTAL AND CONTROL GROUP DURING PRETEST AND POSTTEST AMONG BEDRIDDEN PATIENTS (SIMPLE BAR WITH 2 STANDARD ERROR DIAGRAM)**

**Table 4: Comparison of Post test Modified European Pressure Ulcer Advisory Panel (EPUAP) categorical grading score for pressure ulcers among study group.**

| Modified EPUAP<br>Pressure Ulcer<br>categorical score | Group    |         |           |         |         |         | Chi square test              |
|---|----------|---------|-----------|---------|---------|---------|------------------------------|
|   | Aloevera |         | Olive oil |         | Control |         |                              |
|   | n        | %       | n         | %       | n       | %       |                              |
| Mild  | 4        | 28.57%  | 3         | 30.00%  | 2       | 6.90%   | $\chi^2=15.59p=0.01^{**}(S)$ |
| Moderate  | 8        | 57.14%  | 6         | 60.00%  | 9       | 31.03%  |                              |
| High  | 0        | 0.00%   | 0         | 0.00%   | 9       | 31.03%  |                              |
| Severe Risk   | 2        | 14.29%  | 1         | 10.00%  | 9       | 31.03%  |                              |
| Deep 2nd Degree<br>Ulcers                             | 0        | 0.00%   | 0         | 0.00%   | 0       | 0.00%   |                              |
| Total Incidence                                       | 14       | 100.00% | 10        | 100.00% | 29      | 100.00% |                              |
|   |          |         |           |         |         |         |                              |



**FIGURE 2: DEPICTS THE PRESSURE ULCER OCCURRENCE SIGNS AS PER MODIFIED EPUAP GRADING CRITERIA.**

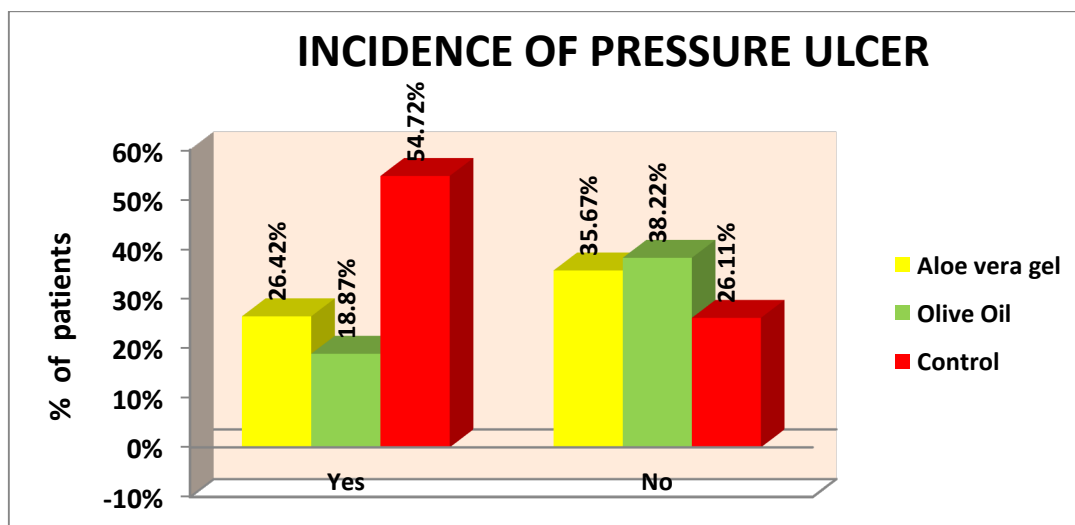


The above table 4 & figure 2 exhibited that 28.57% of aloe vera patients are having mild pressure ulcers signs. 57.14% of olive oil patients are having mild pressure ulcers signs. 31.03 % of control patients are having high and severe signs of pressure ulcers.

Statistically there is a significant difference between Aloe vera gel group , Olive Oil group and control group. Mild level of pressure ulcer is more in aloe vera and olive oil groups than control group. High and Severe signs was present more in control group than aloe vera and olive oil group. It was assessed using chi square test.

**TABLE 5: INCIDENCE OF PRESSURE ULCER**

|                           |     | Group    |        |           |        |         |        | Chi square test                |
|---------------------------|-----|----------|--------|-----------|--------|---------|--------|--------------------------------|
|                           |     | Aloevera |        | Olive oil |        | Control |        |                                |
|                           |     | n        | %      | n         | %      | n       | %      |                                |
| INCIDENCE<br><br>(YES/NO) | Yes | 14       | 26.42% | 10        | 18.87% | 29      | 54.72% | $\chi^2=15.93p=0.001^{***}(S)$ |
|                           |     |          |        |           |        |         |        |                                |
|                           | No  | 56       | 35.67% | 60        | 38.22% | 41      | 26.11% |                                |

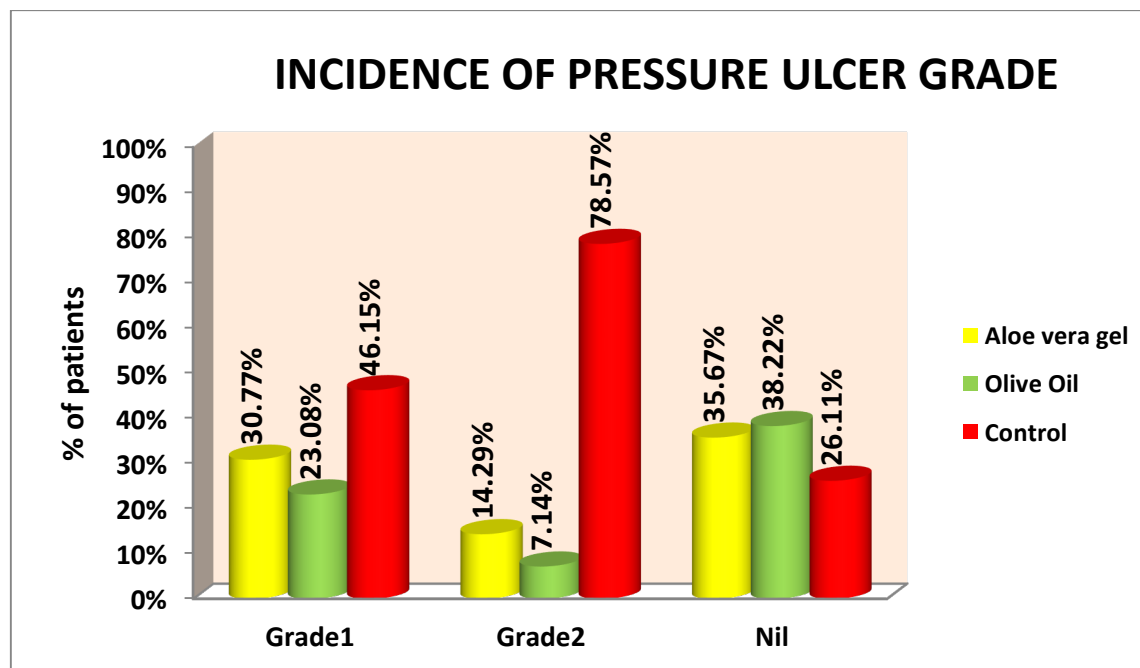


**FIGURE 3: PERCENTAGE DISTRIBUTION REGARDING INCIDENCE OF PRESSURE ULCER AMONG EXPERIMENTAL AND CONTROL GROUP.**

Table 5 and Figure 3 show the incidence of pressure ulcer among study groups. Considering incidence of pressure ulcer; 26.42% of the aloe vera gel patients are having incidence of pressure ulcer. 18.87% of the olive oil patients are having incidence of pressure ulcer. 54.72% of the control patients are having incidence of pressure ulcer.

**TABLE 6: INCIDENCE OF PRESSURE ULCER GRADE AMONG STUDY GROUPS.**

|                    |        | Group    |        |           |        |         |        | Chi square test                |
|--------------------|--------|----------|--------|-----------|--------|---------|--------|--------------------------------|
|                    |        | Aloevera |        | Olive oil |        | Control |        |                                |
|                    |        | n        | %      | n         | %      | n       | %      |                                |
| IF YES<br>(Grades) | Grade1 | 12       | 30.77% | 9         | 23.08% | 18      | 46.15% | $\chi^2=20.06p=0.001^{***}(S)$ |
|                    | Grade2 | 2        | 14.29% | 1         | 7.14%  | 11      | 78.57% |                                |
|                    | Nil    | 56       | 35.67% | 60        | 38.22% | 41      | 26.11% |                                |

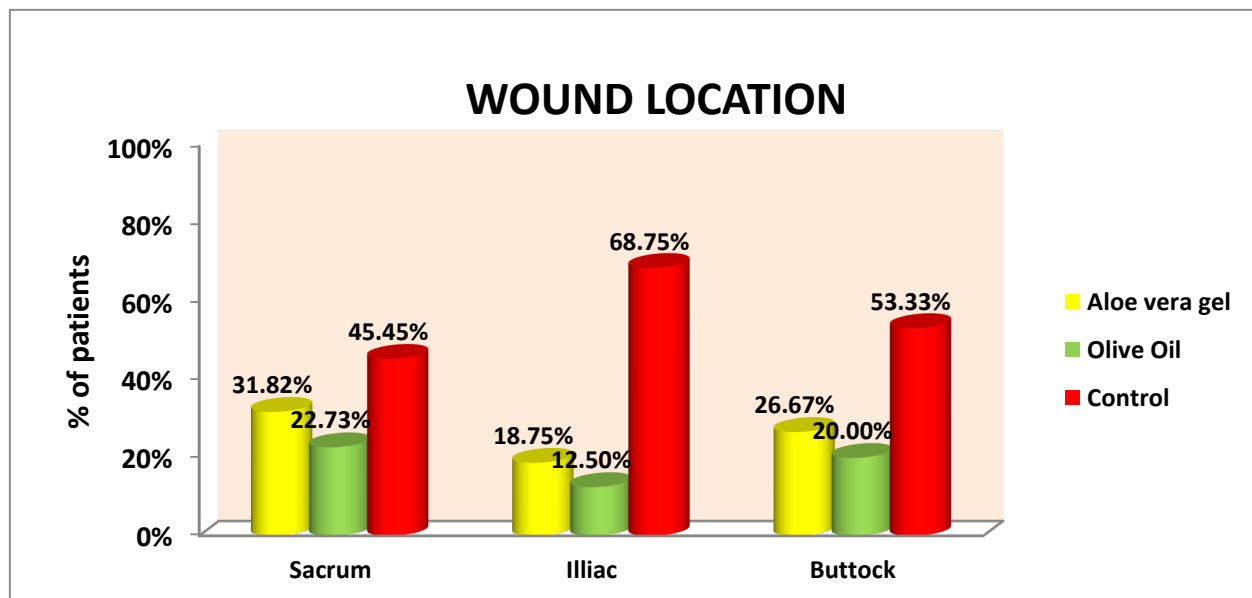


**FIGURE 4: PERCENTAGE DISTRIBUTION REGARDING INCIDENCE OF PRESSURE ULCER GRADE AMONG EXPERIMENTAL AND CONTROL GROUP.**

Table 6 and Figure 4 displayed the grade of pressure ulcer among study groups. Considering Grades of pressure ulcer; only 30.77% of the aloe vera gel patients are having incidence of grade 1 pressure ulcer. 23.08% of the olive oil group patients are having incidence grade 1 pressure ulcer. 46.15% of the control group patients are having incidence of grade 1 pressure ulcer whereas 78.57% of control group subjects had grade 2 pressure ulcers.

**TABLE 7: WOUND LOCATION OF PRESSURE ULCER DEVELOPED AMONG STUDY GROUPS.**

|                       |          | Group    |        |           |        |         |        | Chi square<br>test      |
|-----------------------|----------|----------|--------|-----------|--------|---------|--------|-------------------------|
|                       |          | Aloevera |        | Olive oil |        | Control |        |                         |
|                       |          | n        | %      | n         | %      | n       | %      |                         |
| IF YES wound location | Sacrum   | 7        | 31.82% | 5         | 22.73% | 10      | 45.45% | $\chi^2=2.05p=0.72(NS)$ |
|                       | Illiatic | 3        | 18.75% | 2         | 12.50% | 11      | 68.75% |                         |
|                       | Buttock  | 4        | 26.67% | 3         | 20.00% | 8       | 53.33% |                         |

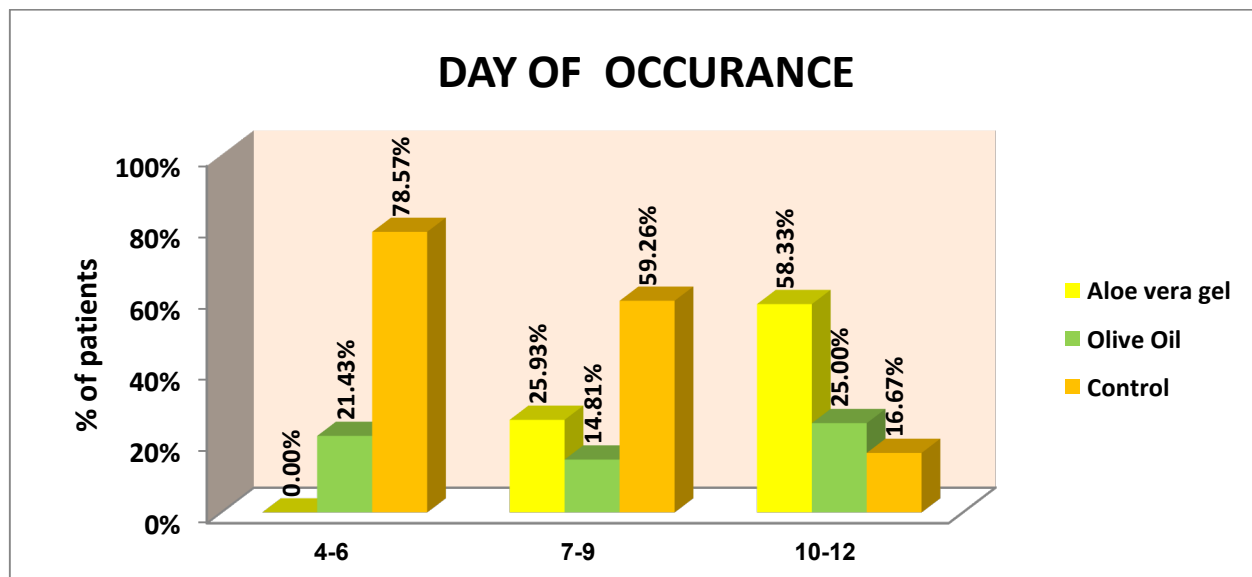


**FIGURE 5: PERCENTAGE DISTRIBUTION OF WOUND LOCATION OF PRESSURE ULCER DEVELOPED AMONG STUDY GROUPS.**

Table 7 and Figure 5 depict the wound location of pressure ulcers occurred among study groups. Considering Wound location 31.82% of the aloe vera gel patients are having sacrum location. 22.73% of the olive oil patients are having sacrum location. 45.45% of the aloe control patients are having sacrum location. Statistically not significant.

**TABLE 8: DAY OF OCCURANCE OF PRESSURE ULCERS AMONG STUDY GROUPS.**

|                             |       | Group    |        |           |        |         |        | Chi square<br><br>test       |
|-----------------------------|-------|----------|--------|-----------|--------|---------|--------|------------------------------|
|                             |       | Aloevera |        | Olive oil |        | Control |        |                              |
|                             |       | n        | %      | n         | %      | n       | %      |                              |
| IF YES day of<br>occurrence | 4-6   | 0        | 0.00%  | 3         | 21.43% | 11      | 78.57% | $\chi^2=13.58p=0.01^{**}(S)$ |
|                             | 7-9   | 7        | 25.93% | 4         | 14.81% | 16      | 59.26% |                              |
|                             | 10-12 | 7        | 58.33% | 3         | 25.00% | 2       | 16.67% |                              |



**FIGURE 6: PERCENTAGE DISTRIBUTION DESCRIBES THE DAY OF OCCURRENCE OF PRESSURE ULCER AMONG STUDY GROUPS.**

Table 8 and Figure 6 Considering Days of occurrence of pressure ulcer, none of the aloe vera gel group patients are having occurrence of pressure ulcer in 4-6 days. 25.00 % of the olive oil group patients are having occurrence of pressure ulcer in 7-9 days. 78.57% of the control group patients are having occurrence of pressure ulcer in 4-6 days. Majority (58.5%) of the aloe vera group participant developed pressure ulcer in 10-12 day.

#### ADVERSE EVENTS:

There were no adverse events associated with this study.