

CLINICAL EVALUATION OF PANCHAVALKALADI KASHAYA IN COMPARISON WITH 5% BETADINE SOLUTION FOR SKIN PREPARATION – A CASE SERIES

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ABSTRACT

In contemporary science there are many antiseptic agents which prevent infection and used for preoperative skin preparation but they are cytotoxic & deleterious to wound healing. *Panchavalkaladi Kashaya* has properties like Antibacterial, Anti-inflammatory, and which accelerates the healing process. *Panchavalkaladi Kashaya* was formulated by combining the drugs *Panchavalkala*, *Shodhita Kasisa*, *Tutta*, and *Sphatika*, which are known to possess *Vranashodana*, *Vranaropana* and *Krimighna* properties. Present study aim is to compare the efficacy of *Panchavalkaladi Kashaya* with 5 % povidone iodine solution in preoperative skin preparation to reduce surgical site infection in clean surgery. Ten individuals of each group were selected irrespective of religion & diet between age group 20-25 years for painting in inguinal region. Results were observed before and after painting (at interval of 30 sec, 60 sec & 120 sec) for microbial load.

Keywords: *Panchavalkaladi Kashaya*, 5% Povidone iodine, Painting, Surgical site infection.

INTRODUCTION

Procedural and SSI (surgical site infection) create difficult & complex clinical scenarios. A source of infection removed from skin surface by making skin preparation before procedure reduces postoperative local complications. Most common skin preparation agents are povidone iodine (aqueous iodophors) & Chlorhexidine gluconate (Alcohol iodophors)¹. Povidone io-

dine contains iodine complexed with solubilizing agent that allows release of free iodine, which acts as an antiseptic agent by destroying microbial protein and DNA²

Povidone iodine is cytotoxic and causes dermatitis with prolonged use³. Irrespective of that fact it is extensively used because of its broad spectrum bactericidal and bacteriostatic property.

Hence there was a need for an innovative polyherbomineral formulation i.e. *Panchavalkaladi Kashaya*. *Panchavalkaladi Kashaya* was formulated by combining the drugs *Panchavalkala*, *Shodhita Kasisa*, *Tutta*, and *Spatika* which are known to possess *Vranashodana*, *Vranaropana* and *Krimigna* property⁴.

Panchavalkaladi Kashaya has been proved safe in acute dermal toxicity, antibacterial action on *S. aureus* and *E. coli* & *Pseudomonas* infection in excised wound model in experimental animal study⁵.

AIM & OBJECTIVE:

To evaluate efficacy of *Panchavalkaladi Kashaya* in comparison with povidone iodine solution in preoperative skin preparation to reduce surgical site infection in clean surgery.

MATERIALS & METHODS:

Source of data: Samples were selected irrespective of religion & diet from SHRI BM Kankanwadi Ayurved Mahavidyala Hospital & Research Centre.

Inclusion criteria:

- Female* 20 – 25 years of age
- With no local infection

OBSERVATION AND RESULT:

Table 1.1

Sr. No	B.T		30 Sec		60 Sec		120 Sec	
	P.K	Beta	P.K	Beta	P.K	Beta	P.K	Beta
1	TNTC	TNTC	10	70	TNTC	83	TNTC	123
2	57	24	1	12	1	2	5	90
3	109	95	TNTC	80	2	TNTC	33	30
4	TNTC	TNTC	NG	1	8	17	4	TNTC
5	110	TNTC	NG	12	4	TNTC	TNTC	TNTC
6	TNTC	35	NG	2	7	21	1	9
7	102	92	NG	1	1	2	NG	85
8	9	FG	NG	45	2	10	5	145
9	7	60	4	10	4	55	8	29
10	150	TNTC	0	NG	1	12	NG	12

*Researcher is a female and could only convince female patients for her study

Exclusion criteria:

-Skin disease, immune compromised individuals

Route and site of drug administration:

-Skin painting of inguinal region 4*5 cm of area

Swab collection:

- Interval: Before Treatment (BT), 30 seconds, 60 seconds & 120 seconds
- Same patient for both groups

Site of application:

- Left inguinal region: Betadine
- Right inguinal region: *Panchavalkaladi Kashaya*

Study design:

A comparative clinical trial

Sample size: 10 Samples in each group

Study drug: *Panchavalkaladi Kashaya*

Control drug: 5% Povidone iodine solution

Investigation: Swab test for microbial load

TNTC – Too Numerous to count = Consider a value 200

NG – No Growth = 0

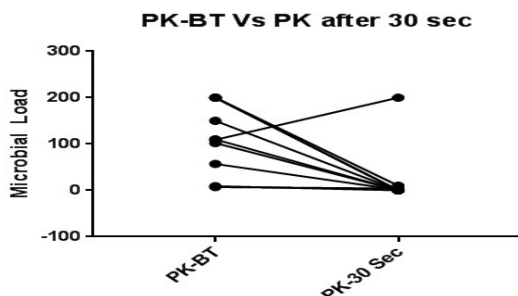
FG – Fungal Growth

Table 1.2

Sr. No	B.T		30 Sec		60 Sec		120 Sec	
	P.K	Beta	P.K	Beta	P.K	Beta	P.K	Beta
1	200	200	10	70	200	83	200	123
2	57	24	1	12	1	2	5	90
3	109	95	200	80	2	200	33	30
4	200	200	0	1	8	17	4	200
5	110	200	0	12	4	200	200	200
6	200	35	0	2	7	21	1	9
7	102	92	0	1	1	2	0	85
8	9	FG	0	45	2	10	5	145
9	7	60	4	10	4	55	8	29
10	150	200	0	0	1	12	0	12

Microbial load analysis for *Panchavalkaladi Kashaya* before treatment & after 30 Seconds (Within the group)

PK-BT	PK-30 Sec
Y	Y
200.0	10.0
57.0	1.0
109.0	200.0
200.0	0.0
110.0	0.0
200.0	0.0
102.0	0.0
9.0	0.0
7.0	4.0
150.0	0.0



Paired t test		
1	Table Analyzed	PK-BT Vs PK after 30 sec
2		
3	Column B	PK-30 Sec
4	vs.	vs.
5	Column A	PK-BT
6		
7	Paired t test	
8	P value	0.0150
9	P value summary	*
10	Significantly different (P < 0.05)?	Yes
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=3 df=9
13	Number of pairs	10
14		
15	How big is the difference?	
16	Mean of differences	-92.9
17	SD of differences	97.93
18	SEM of differences	30.97
19	95% confidence interval	-163 to -22.85
20	R squared (partial eta squared)	0.5
21		
22	How effective was the pairing?	
23	Correlation coefficient (r)	-0.01698

Fig. 1.1 (Microbial Load analysis for PK 0-30 Seconds with itself (BT))

Microbial load for PK before treatment has been put through t-test with PK after 30 seconds.

During first 30 seconds *Panchavalkaladi Kashaya* has been very effective. No growth has

been observed at multiple occasions. Figure 1.1 shows a statistical calculation where P value is

significantly less than 0.05.

Microbial load analysis for *Panchavalkaladi Kashaya* before treatment & after 60 Seconds (Within the group)

PK- BT	PK-60 Sec
Y	Y
200.0	200.0
57.0	1.0
109.0	2.0
200.0	8.0
110.0	4.0
200.0	7.0
102.0	1.0
9.0	2.0
7.0	4.0
150.0	1.0

Paired t test	
1	Table Analyzed PK-BT Vs PK after 60 Sec
2	
3	Column B PK-60 Sec
4	vs. vs.
5	Column A PK- BT
6	
7	Paired t test
8	P value 0.0035
9	P value summary **
10	Significantly different (P < 0.05)? Yes
11	One- or two-tailed P value? Two-tailed
12	t, df t=3.923 df=9
13	Number of pairs 10
14	
15	How big is the difference?
16	Mean of differences -91.4
17	SD of differences 73.68
18	SEM of differences 23.3
19	95% confidence interval -144.1 to -38.69
20	R squared (partial eta squared) 0.631
21	
22	How effective was the pairing?
23	Correlation coefficient (r) 0.4266

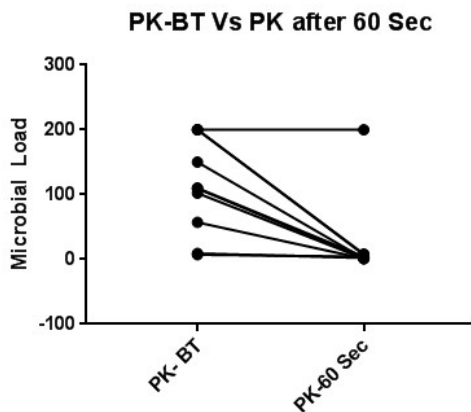


Fig. 1.2 (Microbial Load analysis for PK 0-60 Seconds with itself (BT))

Microbial load for PK before treatment has been put through t-test with PK after 60 seconds. From 0-60 seconds *Panchavalkaladi Kashaya* has been very effective. A very less microbial

growth has been seen. Figure 1.2 shows a statistical calculation where P value is significantly less than 0.05.

Microbial load analysis for *Panchavalkaladi Kashaya* before treatment & after 120 Seconds (Within the group)

PK-BT	PK-120 Sec
Y	Y
200.0	200.0
57.0	5.0
109.0	33.0
200.0	4.0
110.0	200.0
200.0	1.0
102.0	0.0
9.0	5.0
7.0	8.0
150.0	0.0

Paired t test	
1	Table Analyzed PK-BT Vs PK after 120 Sec
2	
3	Column B PK-120 Sec
4	vs. vs.
5	Column A PK-BT
6	
7	Paired t test
8	P value 0.0466
9	P value summary *
10	Significantly different (P < 0.05)? Yes
11	One- or two-tailed P value? Two-tailed
12	t, df t=2.305 df=9
13	Number of pairs 10
14	
15	How big is the difference?
16	Mean of differences -68.8
17	SD of differences 94.39
18	SEM of differences 29.85
19	95% confidence interval -136.3 to -1.278
20	R squared (partial eta squared) 0.3712
21	
22	How effective was the pairing?
23	Correlation coefficient (r) 0.2712

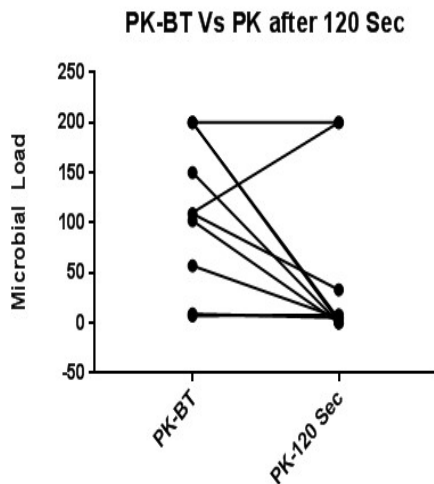


Fig. 1.3 (Microbial Load analysis for PK 0-120 Seconds with itself (BT))

Data shown in Table 1.2 has been put through t-test again for interval 0-120 Seconds. After 60 seconds a microbial growth was observed.

Figure 1.3 shows a significant improvement when compared to the data before treatment.

Microbial load analysis for *Panchavalkaladi Kashaya* Vs Betadine after 30 Seconds (In between the group)

Betadine after 30	PK after 30 Sec
Y	Y
70	10
12	1
80	1
1	0
12	0
2	0
1	0
45	0
10	4
0	0

Unpaired t test	
1	Table Analyzed Betadine Vs PK After 30 Sec
2	
3	Column B PK after 30 Sec
4	vs. vs.
5	Column A Betadine after 30
6	
7	Unpaired t test
8	P value 0.0373
9	P value summary *
10	Significantly different (P < 0.05)? Yes
11	One- or two-tailed P value? Two-tailed
12	t, df t=2.249 df=18
13	
14	How big is the difference?
15	Mean ± SEM of column A 23.3 ± 9.598, n=10
16	Mean ± SEM of column B 1.6 ± 1.013, n=10
17	Difference between means -21.7 ± 9.651
18	95% confidence interval -41.98 to -1.424
19	R squared (eta squared) 0.2193
20	
21	F test to compare variances
22	F, DFn, Dfd 89.72, 9, 9
23	P value <0.0001
24	P value summary ****
25	Significantly different (P < 0.05)? Yes

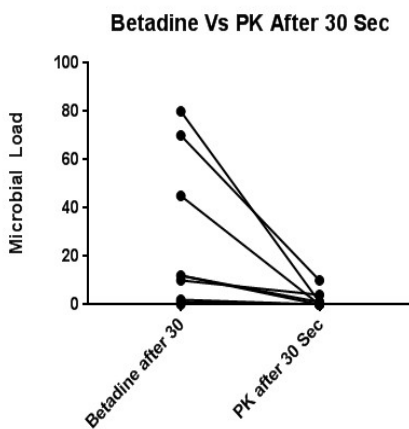


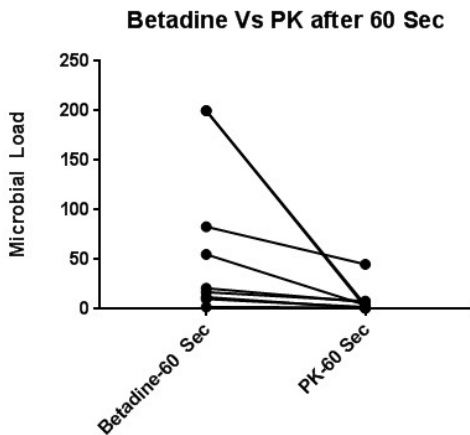
Fig. 1.4 (Microbial Load analysis for Panchavalkaladi Kashaya Vs Betadine after 30 seconds)

Data shown in Table 1.2 has been put through t-test. During first 30 seconds *Panchavalkaladi Kashaya* has been very effective. No growth has

been observed at multiple occasions. Figure 1.4 shows a statistical calculation where P value is significantly less than 0.05.

Microbial load analysis for *Panchavalkaladi Kashaya* Vs Betadine after 60 Seconds (In between the group)

Betadine-60 Sec	PK-60 Sec
Y	Y
83	45
2	1
200	2
17	8
200	4
21	7
2	1
10	2
55	4
12	1



Unpaired t test	
1	Table Analyzed
2	Betadine Vs PK after 60 Sec
3	Column B
4	PK-60 Sec
5	vs.
6	vs.
7	Column A
8	Betadine-60 Sec
9	Unpaired t test
10	P value
11	0.0494
12	P value summary
13	*
14	Significantly different (P < 0.05)? Yes
15	One- or two-tailed P value?
16	Two-tailed
17	t, df
18	t=2.108 df=18
19	How big is the difference?
20	Mean ± SEM of column A
21	60.2 ± 24.64, n=10
22	Mean ± SEM of column B
23	7.5 ± 4.241, n=10
24	Difference between means
25	-52.7 ± 25.01
26	95% confidence interval
27	-105.2 to -0.1657
28	R squared (eta squared)
29	0.1979
30	F test to compare variances
31	F, DFn, Dfd
32	33.77, 9, 9
33	P value
34	<0.0001
35	P value summary
36	****
37	Significantly different (P < 0.05)? Yes

Fig. 1.5 (Microbial Load analysis for PK Vs Betadine after 60 seconds)

Data shown in Table 1.2 has been put through t-test. Again, during 60 seconds *Panchavalkaladi Kashaya* has been very effective. A very less

microbial growth has been seen. Figure 1.5 shows a statistical calculation where P value is significantly less than 0.05.

Microbial load analysis for *Panchavalkaladi Kashaya* Vs Betadine after 120 Seconds (In between the group)

Betadine-120 Sec	PK-120 Sec
Y	Y
123	200
90	5
30	33
200	4
200	200
9	1
85	0
145	5
29	8
12	0

Unpaired t test		
1	Table Analyzed	Betadine Vs PK after 120 Sec
2		
3	Column B	PK-120 Sec
4	vs.	vs.
5	Column A	Betadine-120 Sec
6		
7	Unpaired t test	
8	P value	0.1957
9	P value summary	ns
10	Significantly different (P < 0.05)?	No
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=1.344 df=18
13		
14	How big is the difference?	
15	Mean ± SEM of column A	92.3 ± 23.15, n=10
16	Mean ± SEM of column B	45.6 ± 25.91, n=10
17	Difference between means	-46.7 ± 34.75
18	95% confidence interval	-119.7 to 26.31
19	R squared (eta squared)	0.09119
20		
21	F test to compare variances	
22	F, DFn, Dfd	1.252, 9, 9
23	P value	0.7430
24	P value summary	ns
25	Significantly different (P < 0.05)?	No

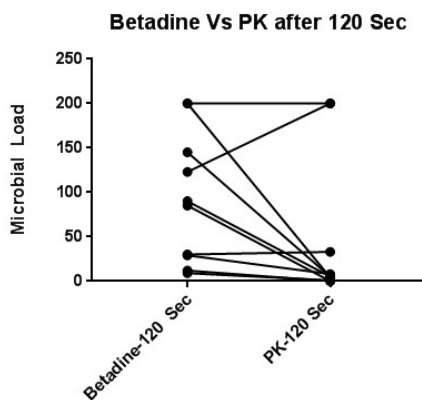


Fig. 1.6 (Microbial Load analysis for PK Vs Betadine after 120 seconds)

Data shown in Table 1.2 has been put through t-test again for interval 60-120 Seconds. After 60 seconds a microbial growth was observed. Figure 1.6 shows a statistical calculation where P value is higher than 0.05. Keeping in mind

that no concentration factor was considered while preparing the drug, it is possible if a higher concentration of the drug is used, results could be better at this stage. This could be a scope of enhancement.

Microbial load analysis for Betadine before treatment & after 30 Seconds (Within the group)

Betadine-BT	Betadine-30 Sec
Y	Y
200.0	70.0
24.0	12.0
95.0	80.0
200.0	1.0
200.0	12.0
35.0	2.0
92.0	1.0
70.0	45.0
60.0	10.0
200.0	0.0

Paired t test	
1	Table Analyzed
2	Betadine-BT Vs Betadine after 30 Sec
3	Column B
4	Betadine-30 Sec
5	vs.
6	vs.
7	Column A
8	Betadine-BT
9	Paired t test
10	P value
11	0.0043
12	P value summary
13	**
14	Significantly different (P < 0.05)?
15	Yes
16	One- or two-tailed P value?
17	Two-tailed
18	t, df
19	t=3.788 df=9
20	Number of pairs
21	10
22	How big is the difference?
23	Mean of differences
24	-94.3
25	SD of differences
26	78.73
27	SEM of differences
28	24.9
29	95% confidence interval
30	-150.6 to -37.98
31	R squared (partial eta squared)
32	0.6145
33	How effective was the pairing?
34	Correlation coefficient (r)
35	0.04933
36	P value (one tailed)
37	0.4462
38	P value summary
39	ns
40	Was the pairing significantly effective? No

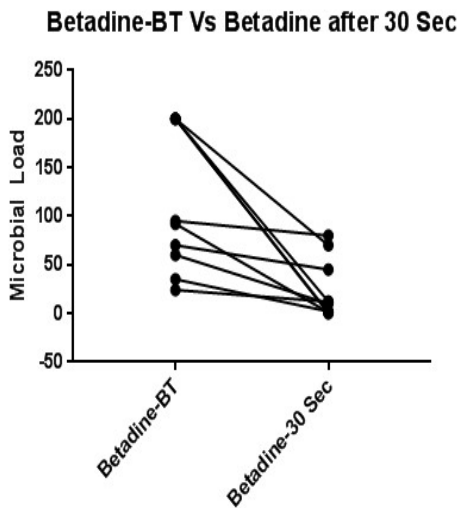


Fig. 1.7 (Microbial Load analysis for Betadine 0-30 Seconds with itself (BT))

Microbial load for Betadine before treatment was put through a T-test with Betadine after 30 Seconds. P value is significantly less than 0.05. Figure 1.7 shows a statistical calculation.

Microbial load analysis for Betadine before treatment & after 60 Seconds (Within the group)

Betadine-BT	Betadine-60 Sec
Y	Y
200.0	83.0
24.0	2.0
95.0	200.0
200.0	17.0
200.0	200.0
35.0	21.0
92.0	2.0
70.0	10.0
60.0	55.0
200.0	12.0

Paired t test	
1	Table Analyzed
2	Betadine-BT Vs Betadine after 60 Sec
3	Column B
4	Betadine-60 Sec
5	vs.
6	vs.
7	Column A
8	Betadine-BT
9	Paired t test
10	P value
11	0.0747
12	P value summary
13	ns
14	Significantly different (P < 0.05)?
15	No
16	One- or two-tailed P value?
17	Two-tailed
18	t, df
19	t=2.015 df=9
20	Number of pairs
21	10
22	How big is the difference?
23	Mean of differences
24	-57.4
25	SD of differences
26	90.06
27	SEM of differences
28	28.48
29	95% confidence interval
30	-121.8 to 7.028
31	R squared (partial eta squared)
32	0.311
33	How effective was the pairing?
34	Correlation coefficient (r)
35	0.2994
36	P value (one tailed)
37	0.2003
38	P value summary
39	ns
40	Was the pairing significantly effective? No

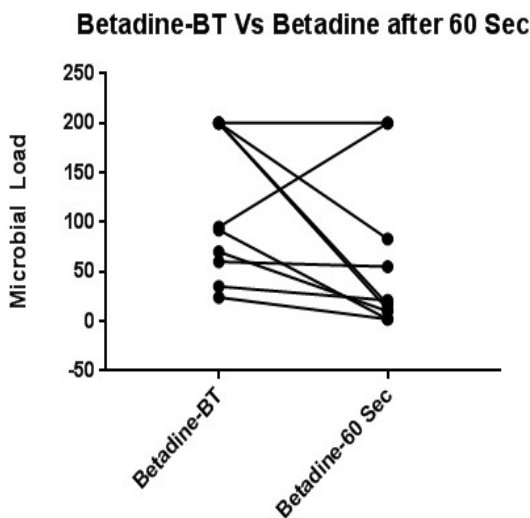


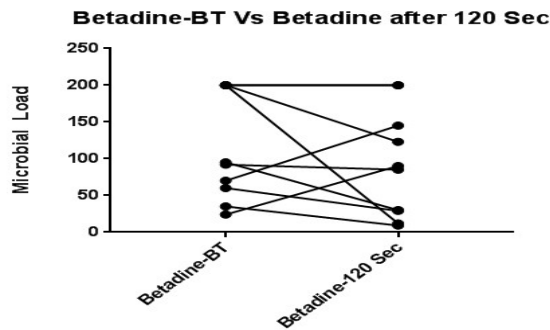
Fig. 1.8 (Microbial Load analysis for Betadine 0-60 Seconds with itself (BT))

Microbial load for Betadine before treatment was put through a T-test with Betadine after 60

Seconds. P value is slightly higher than 0.05. Figure 1.8 shows a statistical calculation.

Microbial load analysis for Betadine before treatment & after 120 Seconds (Within the group)

Betadine-BT	Betadine-120 Sec
Y	Y
200.0	123.0
24.0	90.0
95.0	30.0
200.0	200.0
200.0	200.0
35.0	9.0
92.0	85.0
70.0	145.0
60.0	29.0
200.0	12.0



Paired t test	
1	Table Analyzed
2	Column B
3	vs.
4	Column A
5	Paired t test
6	P value
7	P value summary
8	Significantly different (P < 0.05)?
9	One- or two-tailed P value?
10	t, df
11	Number of pairs
12	How big is the difference?
13	Mean of differences
14	SD of differences
15	SEM of differences
16	95% confidence interval
17	R squared (partial eta squared)
18	How effective was the pairing?
19	Correlation coefficient (r)
20	P value (one tailed)
21	P value summary
22	Was the pairing significantly effective? No

Fig. 1.9 (Microbial Load analysis for Betadine 0-120 Seconds with itself (BT))

Microbial load for Betadine before treatment was put through a T-test with Betadine after 120 Seconds. P value is higher than 0.05. Figure 1.8 shows a statistical calculation.

DISCUSSION

Most common skin preparation agents are povidone iodine (aqueous iodophors) and Chlorhexidine gluconate (Alcohol iodophors). They have broad spectrum bacteriostatic and bactericidal action. Povidone iodine contains iodine complexed solubilizing agent that allows release of free iodine, which acts as antiseptic agent by destroying microbial protein and DNA. They are still cytotoxic and can cause dermatitis due to prolonged use., hence the need to explore

a polyherbomineral formulation. *Panchavalkaladi Kashaya* was formulated by combining the drugs *Panchavalka*, *Shodhita Kasisa*, *Tutta* and *Spatika*. These are *Shita veerya*, *Ruksha*, *Kashaya rasa*, *Pitta* and *Kaphagna*⁶ and have *Vranashodana*, *Vranaropana* and *Krimigna* property.⁷ The ingredients of formulation have been more effective than Betadine during first 60 seconds. No bacterial growth has been detected for few samples during first 30 seconds. After 60 Se-

conds, results are less effective, this could be because of undefined concentration as like 5% Betadine. In Vitro anti-microbial study of *Panchavalkaladi Kashaya* shows antibacterial activity against *S.aureus*, *E. coli* and *P. Aeruginosa K. pneumoniae* organism, both in disc diffusion method and MIC⁴. But has not been proved to have broad spectrum antimicrobial property. It has also been observed that *Panchavalkaladi Kashaya* acts better over fungal growth than Betadine.

In this study *Panchavalkaladi Kashaya* has been very effective during first 60 seconds, there are scope of enhancement and can lead to better results if a higher concentration of the drug is used.

CONCLUSION

The goal of preoperative skin preparation is to reduce the incidences of SSI in a safe, user friendly and cost effective manner. Post operative infection often requires repeat surgery and prolonged hospitalization and it may compromise ultimate surgical outcome. *Panchavalkaladi Kashaya* has better antimicrobial and antiseptic action in skin preparation in short life time of 60 seconds as compared to povidone iodine solution.

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Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Parul Yadav Et Al: Clinical Evaluation of Panchavalkaladi Kashaya In Comparison With 5% Betadine Solution for Skin Preparation – A Case Series. International Ayurvedic Medical Journal {online} 2018 {cited February, 2018} Available from: http://www.iamj.in/posts/images/upload/344_355.pdf