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Efficacy of detoxifying and palliative Ayurvedic treatment on survival and quality of life in triple negative breast cancer patients

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Triple Negative Breast Cancer (TNBC) accounts for ~10-20% of invasive breast cancers and has an early recurrence and aggressive metastases. It is a heterogeneous disease based on immunohistochemistry as estrogen, progesterone, and human epidermal growth factor-2 receptors are negative. Thus, hormonal treatment is not offered to TNBC patients after completion of conventional treatment like other types of breast cancer patients. In this scenario, alternative medicines like Ayurveda are the day's need. According to Ayurveda, vitiated *Vata, Pitta*, and *Kapha* impair *Jatharagni* (digestive power) and *Dhatvagni* (digestive power of each tissue), disrupting dhatu metabolism (*Rasa* to *Meda*). This forms deep, firm, slow-growing, non-suppurative tumors at impaired sites like the breast, with progressive *dhatu* (deeper tissue) involvement (*Dhatugatavastha*), which is known as *Dushta Stana Granthi* (malignant breast nodes) or *Arbuda* (malignant breast tumour). In such a situation, Ayurveda describes *Shamana* (*Dosha* pacification), *Rasayana* (Rejuvenation), and *Shodhana i.e., Panchakarma* (body detoxification) as the main treatment modalities. Oral Ayurvedic medicines (OAM) consisting of *Shamana* and *Rasayana* are known to improve quality of life and immunity boosting in many diseases including cancer whereas *Panchakarma* (PNK) detoxifies body and thus helps to minimize the risk of recurrence. The main aim of this study was to study the efficacy of Ayurvedic treatment as well as comparing effect of treatment modalities *viz., Shamana* with *Rasayana* (SR) and *Shamana* with *Rasayana* and *Panchakarma* (SRP) on survival and Quality of life (QoL) in TNBC patients. In this retrospective study, 68 patients diagnosed with TNBC, irrespective of stage and grade, with ongoing or completed conventional treatment and taken Ayurvedic treatment for more than 6 months were included. QoL was studied by using standard questionnaires while Disease-free Survival (DFS) and Overall survival (OS) were assessed by radiological and biochemical parameters. DFS was found in maximum patients (75%) and progression in only 25% of patients also highlight the efficacy of Ayurvedic treatment to control the disease. Longer DFS and OS were seen in the patients treated with SRP as compared to SR. Significant improvement in functional, symptom, global, and Karnofsky performance scores of all patients indicated improved QoL and well-being after Ayurvedic treatment. These results are indicative of efficacy of Ayurvedic treatment to increase survival and improve QoL of TNBC patients. Especially, SRP treatments are more beneficial to increase DFS and OS thus emphasizing the necessity of detoxifying PNK treatment in addition to OAM in TNBC patients.

Keywords: *Dushta Stana granthi*, *Dushta Stana Arbuda*, *Dhatugata avastha*, Oral Ayurvedic treatment, *Panchakarma*, Quality of life, Survival, Triple-negative breast cancer

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Triple Negative Breast Cancer (TNBC) is a heterogeneous disease based on immunohistochemistry (IHC) having estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2), all negative. TNBC exhibits a distinct molecular profile, a highly aggressive behaviour, unique patterns of metastasis, and lack of targeted therapies. Among all types of breast cancer, the incidences of TNBC account for 10 to 20% worldwide[1]. TNBC is characterized by younger age, higher histological grade, a higher rate of positive lymph nodes, bigger tumor size, higher clinical stage at diagnosis, quicker and easier recurrence and metastasis, and lower 5-year disease–free survival (DFS) rate and 5-year overall survival (OS) rate[2]. The 5-year survival rate is of ~65% for regional tumors and 11% for those that have spread to

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distant organs[3]. From Ayurvedic perspective, improper life style and dietary habits, *Krimi* (worm infestation), lack of physical activity, mental stress and positive family history were supposed to be the causative factors in life-style disorders like TNBC[4]. Ingestion of etiological factors leads to the aggravation of the three *doshas*-*Vata*, *Pitta*, and *Kapha*- which subsequently impair *Jatharagni* (digestive/metabolic fire) and *Dhatvagni* (metabolic activity at the tissue level). Vitiation of the *Dhatvagni* of *Rasa, Rakta, Mamsa*, and *Meda dhatus* (plasma, blood, muscle, and adipose tissues) results in abnormal cellular proliferation and tumor formation in affected organs, such as the breast. These pathological growths are described in Ayurveda as *Dushta Stana Granthi* (malignant breast nodules) or *Dushta Stana Arbuda* (malignant tumors of the breast). Clinically, these tumors exhibit features such as being *Vrittam* (round), *Sthiram* (immovable), *Manda ruja* (slightly painful), *Mahan* (big), *Analpa moolam* (deep-seated), *Chira vruddhi* (slowly growing), and *Apakam* (non-suppurating) in nature which has a tendency of *Dhatugatavastha* (stage of embedding in deeper tissues and vitiating them).

In *Dushta stana granthi/ arbuda*, the presence of homologous, synergistic interaction among causative factors, and aggravated *tridoshas*, the vitiation of *Rasa, Mamsa, Meda* and *Shukra dhatu* (Lymphatic, muscular, adipose tissue and reproductive system), interact quickly leading to early manifestation and aggressive nature of TNBC pathogenesis[5]. Vitiation of *Rasadhatu* is considered a primary causative factor in the pathogenesis of breast cancer, as the breast milk (*Stanya*) is regarded as one of the *upadhatus* (subordinate tissues) of *Rasadhatu*. Psychological factors such as anxiety, chronic mental stress, and emotional trauma are known to disturb *Rasadhatu*[4], potentially leading to the early onset and aggressive progression of breast cancer within 3 to 5 years. Based on our research experience spanning the last 30 years, we have consistently observed a history of chronic mental stress in patients diagnosed with TNBC, which reinforces this classical understanding.

Thus, the *Ayurvedic* treatment which keeps *doshas* and *dhatus* in equilibrium with *Shamana chikitsa*, detoxifies the deeper tissues of body with *Shodhana chikitsa -Panchakarma* (PNK) and enhances immune system with *Rasayana chikitsa* is beneficial in an aggressive disease like TNBC. Hence, this retrospective study was planned to find out the efficacy of Ayurvedic treatment to improve survival, quality of life and minimize the risk of the recurrence in TNBC.

Materials and Methods

Study design

It is a retrospective observational, single centric study. It was approved by Institutional Ethics Committee of Bharatiya Sanskriti Darshan Trust, Wagholi, Pune (dated 04/08/2006).

Inclusion criteria

- Patients between the age group 20 to 80 years.
- Breast cancer patients with immunohistochemistry ER-PR-Her2 Negative status.
- TNBC patients of all stages and grades.
- TNBC patients who were undergoing or completed conventional treatment and treated with adjunct Ayurvedic treatment at ICTRC, Wagholi, Pune for more than 6 months.

Exclusion criteria

- Male breast cancer patients.
- TNBC Patients with uncontrolled comorbidities like DM, HTN etc.

Source of data

The patients who have attended OPD and IPD of BSDT's Integrated Cancer Treatment and Research Centre (ICTRC), Wagholi, Pune during the period of year 2004 to year 2018 with triple negative breast cancer diagnosis, fulfilling the inclusion criteria were enrolled in the study. A data was collected from pre-designed proforma containing the details of socio-demographic data, chief complaints, personal history, family history, medical history, conventional treatment and adjunct Ayurvedic intervention.

Grouping

Based on the Ayurvedic treatment modalities, patients were divided into two groups *viz.*, Group 1-SR- Patient those who were treated with a combination of *Shamana* and *Rasayana* treatment and Group 2- SRP- Patients who were treated with additional PNK treatment along with *Shamana* and *Rasayana* treatment.

Treatment regimen

All 68 TNBC patients were treated with *Shamana chikitsa* consisting of *Mauktikayukta Kamdudha Vati* (MKD), *Praval Pishti Vati* (PPV) and *Arogyavardhini Vati* (AV). *Rasayana chikitsa* was prescribed in the form of *Atharva Suvarna Bhasmadi Vati* (ASBV) [201921018272 (Indian Patent published), PCT/IB2020/051114 (International Patent), 17/609,

535 (US patent application no)], *Atharva Shatavari Kalpa* (ASK) and *Triphala Guggul* (TG).

PNK included *Basti* (medicated enema) and *Vamana* (induced emesis). Details of PNK treatment are given in Table 1.

Outcome measures

The assessment of all patients was done before (Time point A) and after (Time point B) the Ayurvedic treatment. Quality of life (QoL) was studied on the basis of the Core Quality of Life questionnaire (QLQ-C30) of European Organization for Research and Treatment of Cancer (EORTC) and the performance status was also studied with Karnofsky Performance Score (KPS). Their survival was assessed based on the periodic radiological investigations *viz*., Mammography, Ultrasonography of Abdomen and Pelvis (USG A+P) and whole-body Positron Emission Tomography and Computed Tomography (PET-CT) scan. Functions of body elements and vital organs were assessed periodically with haematological and biochemical parameters *viz.*, Complete Blood Count (CBC), Liver Function Test (LFT), and Kidney Function Test (KFT).

Data analysis

The data stored and developed in Microsoft Excel 2019 and presented as Mean ± SEM. The KPS interpreted in 0-100 scale while QLQ C-30 score was interpreted as functional, symptom and global items and the raw score was linearly transformed into 0-100 scale according to scoring manual of EORTC. The difference of mean of KPS and QLQ-C 30 of both the groups was measured with paired t test. Likewise, the difference of mean score in all TNBC patients (n=68) who received Ayurvedic treatment assessed by paired 't' test. The comparison of the groups (SR, SRP, combined-SR+SRP) was evaluated by unpaired t-test. The statistical analysis was done by using GraphPad Instat software, version 3.0. and p value at <0.05 considered as statistically significant. The survival of patients in both groups was assessed with Kaplan Meier curve by using GraphPad prism, Version 8.

Results

Out of 68 patients, n=40 (58.8%) patients belonged to Group 1-*Shamana* and *Rasayana* (SR) treatment, while n=28 (41.2%) patients to Group 2- *Shamana*, *Rasayana*, and *Panchakarma* (SRP) treatment modalities. The distribution of patients in both groups based on age, histopathology, stage-grade, and conventional treatment taken is illustrated in Table 2.

In the SRP group, n=23 patients received *Basti* treatment, while *Vamana* was given to 3 patients, and a combination of *Basti* and *Vamana* in 2 patients. Among 28 patients, half of the patients (n=14) underwent PNK treatment for multiple times and 14 patients underwent PNK once.

Assessment of TNBC patients treated with Ayurvedic modalities

The SR+SRP (combined) and group-wise (individual SR and SRP) effect on the QoL in TNBC patients after Ayurvedic treatment (irrespective of the modality) is depicted in Figure 1. Extremely significant improvement in the KPS was seen in SR+SRP group ($p=0.0009$) and significant improvement in the SR ($p=0.031$) and SRP ($p=0.0113$). Extremely significant

Table 1 — Details of Panchakarma treatment

Panchakarma	Type	Properties
Basti (Medicated Enema) *	*Krumighna Matra Basti*	Anthelmintic, wound healing, anti-inflammatory, alleviates *Kapha Vata dosha* [11,3/94, 114, 120-121]
	Krumighna Anuvasan Basti	Mentioned above
	Krumighna Niruha Basti	Anthelmintic, alleviates *Vata*, *Kaphadosha*, anti-inflammatory, immunomodulatory, laxative [11,1/43,112; 2/93; 3/107-108, 200]
	Erandmooladi Niruha Basti	Anti-inflammatory, analgesic, alleviates *Kapha Vata dosha*, immunomodulatory, strengthens the body. [11,1/90-92, 163-164; 3/8-10,45-46, 49, 63-66,144 – 146, 231]
	Erandmooladi Anuvasan Basti	Laxative, anti-inflammatory, alleviates *Vata – Kaphadosha*, Anthelmintic [11, 3/49, 62-63, 8/64-65]
Vamana- (Induced Emesis)	*Yashtimadhu* (*Glycyrrhiza glabra* L.)	Anti-inflammatory, Anti-ulcer, Anti toxic, alleviates diseases of *Vata-Pitta-Raktadosha* [11,1/146]

*Krumighna Matra/ Anuvasan basti- *Nimba* (*Azadirachta indica* A.Juss.) + *Nirgundi* (*Vitex negundo* L) + *Karanja* (*Pongamia glabra* Vent.)
**Krumighna Niruha Basti- Vidang* (*Embelia ribes* Burm.f.) + *Shigru* (*Moringa pterygosperma* Gaertn.) + *Musta* (*Cyperus rotundus* L.) + *Dantimoola* (*Baliospermum montanum* Müll.Arg.) + *Triphala*
**Erandmooladi Niruha Basti- Erandmoola* (roots of *Ricinus communis* L.) + *Dashmoola (Laghu Panchamoola and Bruhat Panchamoola*) + *Bala* (*Sida cordifolia* L.) + *Punarnava* (*Boerhavia diffusa* L.) + *Guduchi* (*Tinospora cordifolia* (Willd.) Hook.f. & Thomson) + *Rasna* (*Alpinia galangal* (L.) Willd.) + *Gokshura* (*Tribulus terrestris* L) + *Shatpushpa* (*Pimpinella anisum* L.)

improvement in Functional score was seen in SR+SRP ($p<0.0001$) and in SRP ($p<0.0001$). Global score showed extremely significant improvement in SR+SRP ($p<0.0001$) and SRP ($p<0.0005$) while very significant improvement in SR ($p=0.0013$). Extremely significant reduction seen in Symptom score in SR+SRP ($p<0.0001$) and in SRP group ($p=0.0004$). These all results were indicative of efficacy of Ayurvedic treatment in improving QoL of TNBC patients.

The effects of SR+SRP, SR and SRP on hematological and biochemical parameters in TNBC patients are depicted in the Figure 2 a,b. Although statistically significant decrease was observed in platelet count ($p=0.02$) and alkaline phosphatase (ALP) levels ($p=0.04$) in SR+SRP group, these values remained within normal range. In contrast, SRP group showed a highly significant improvement in Hemoglobin level ($p=0.003$) and significant improvement in SGPT ($p=0.01$).

The details of comparative analysis between both the groups (SR and SRP) are demonstrated in Figure 3. Though haematological and biochemical parameters did not show a significant change in patients from both groups, however, there was increase in Hb and WBC levels and reduction in ALP level was seen in SRP as compared to SR group, though statistically not significant.

The outcome of the radiological investigations in these patients is delineated in Table 3. DFS and OS were assessed in patients of SR and SRP groups. Among 68 patients, n=61 patients were available with radiological investigation (Mammography, USG A+P, X-ray Chest, PET-CT) to ascertain their disease status while rest of the patients (n=7) were undergone clinical examination to evaluate their disease status. After this assessment, it was found that the disease was under control in 75% and progressive in 25% of TNBC patients.

Table 2 — Ayurvedic treatment group-wise distribution of TNBC patients

Parameters		No. of patients (%)	
		SR (40)	SRP (28)
Age (years)	21-40	10 (25)	14 (50)
	41-60	18 (45)	12 (42.86)
	61-80	12 (30)	02 (7.14)
Histopathology	Invasive Ductal Carcinoma	39 (97.5)	24 (85.72)
	Medullary Carcinoma	00 (0)	02 (7.14)
	Invasive Mammary Carcinoma	01 (2.5)	00 (00)
	Metaplastic spindle cell Carcinoma	00 (0)	01 (3.57)
	Cribriform	00 (0)	01(3.57)
Stage	0	01 (2.5)	00 (0)
	I	03 (7.5)	05 (17.85)
	II (IIA+IIB+IIC)	26 (65)	16 (57.15)
	III (IIIA+IIIB+IIIC)	09 (22.5)	07 (25)
	IV	01(2.5)	00 (00)
Grade	I	00 (0)	04 (14.28)
	II	06 (15)	17 (60.72)
	III	34 (85)	07 (25)
Conventional treatment taken	Only Surgery	00 (0)	01(3.57)
	Surgery + Chemotherapy	17 (42.50)	06 (21.43)
	Surgery + Chemotherapy + Radiotherapy	22 (55)	20 (71.43)
	Surgery + Radiotherapy	01 (2.50)	01(3.57)

Survival analysis of TNBC patients after Ayurvedic treatment

Survival analysis of both groups after Ayurvedic treatment modalities is graphically presented in Figure 4. A prolonged survival is seen in SRP group patients as compared to SR group. The remarkable increase in the survival for more than 10 years was seen in the patients of SRP group with respect to DFS (46% verses 15%) and OS (50% verses 33%) as

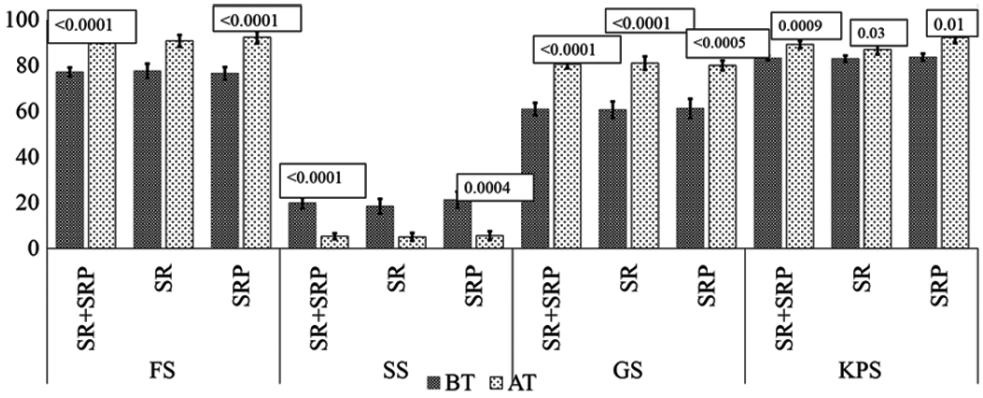

Fig. 1 — Groupwise analysis of Quality of life (QoL) parameters - Functional score (FS), Symptom score (SS), and Global score (GS), Karnofsky Performance score (KPS) in TNBC Patients treated with OAM and PNK. The mean values are compared by paired t test. $p<0.05$ considered significant

compared to the SR group. The percentage of deaths was also less in the SRP group (14%) as compared to SR group (30%) within 1 year.

Discussion

The prevalence of breast cancer cases in India has been observed to be on the rise. Approximately, 10-

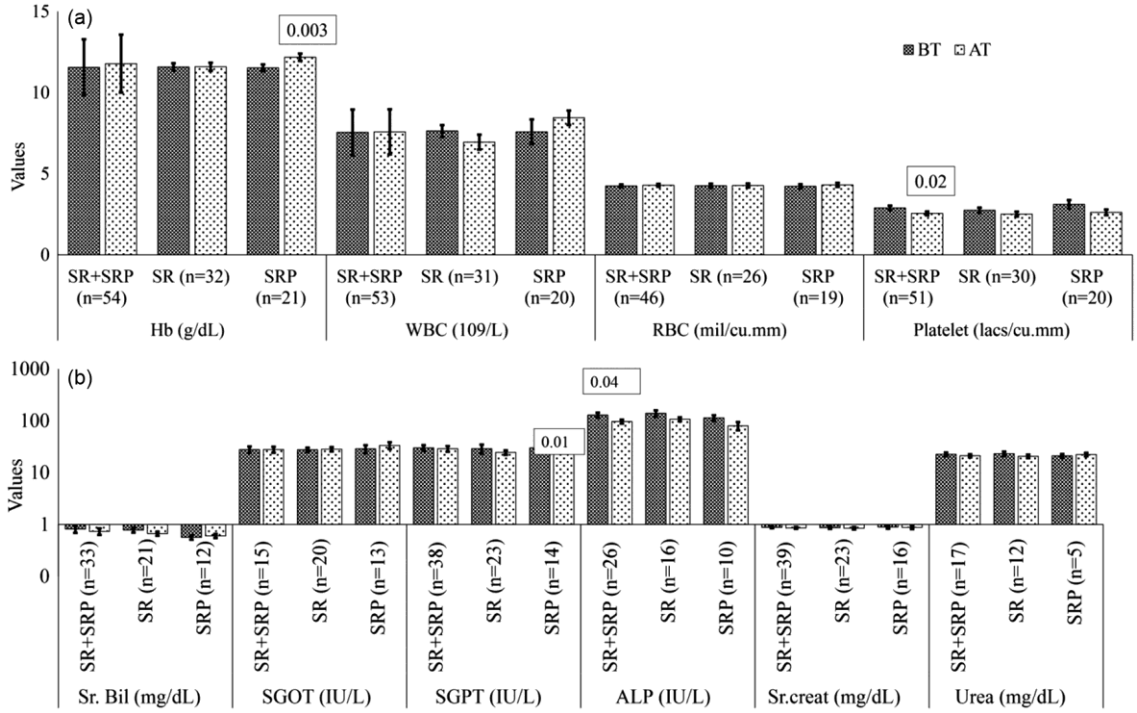

Fig. 2 — (a) Analysis of mean values of Haematological parameters in SR+SRP, SR and SRP groups before and after Ayurvedic treatment. (b) Analysis of mean values of Biochemical parameters in SR+SRP, SR and SRP groups before and after Ayurvedic treatment. The mean values are compared by paired t test. $p<0.05$ considered significant.

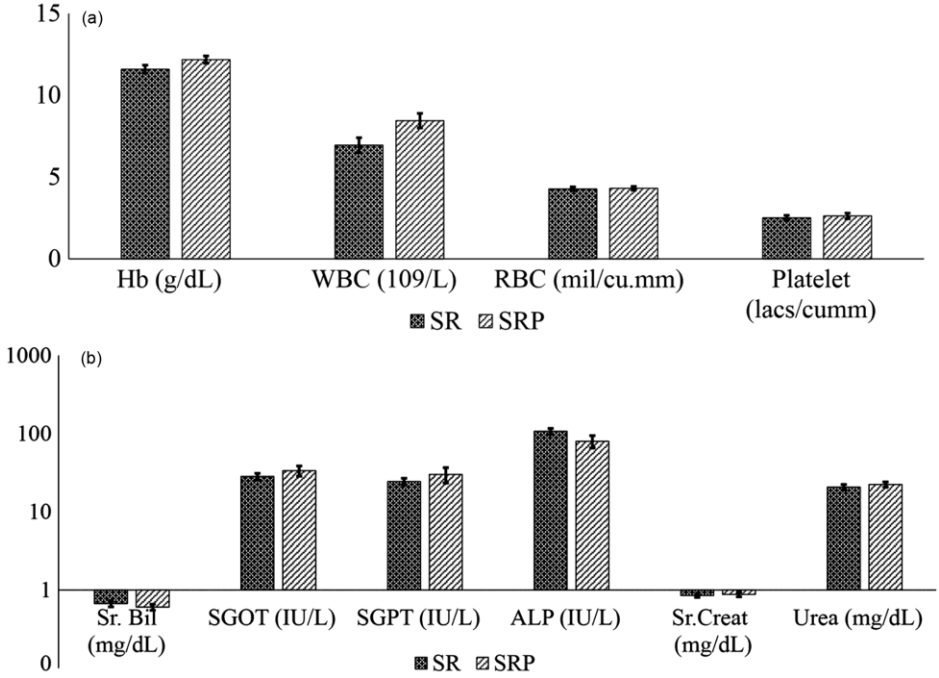

Fig. 3 — Comparative analysis of mean values of SR and SRP treated groups (a) effect on Haematological and (b) effect on Biochemical parameters. The difference of means is compared by Unpaired t test. $p<0.05$ considered significant.

15% of breast carcinomas are known to be of the TNBC sub-type, characterized by onset at a younger age, high mean tumour size, and higher-grade tumours. It is aggressive, associated with poor prognosis and a high risk of relapse with short progression–free survival (PFS) and overall survival (OS). Compared with other subtypes of breast cancer, the survival time of TNBC patients is shorter, and the mortality rate is 40% within the first 5 years after diagnosis. TNBC is highly invasive, and approximately 46% of TNBC patients will have distant metastasis. Distant metastasis typically manifests around the third year after diagnosis. The median duration until relapse in non-TNBC patients ranges from 35 to 67 months, whereas in TNBC patients, it is notably shorter, spanning from 19 to 40 months. The mortality rate among TNBC patients within three months after recurrence is alarmingly high, reaching 75%[6].

In this retrospective study, the maximum number of patients of grade III and stage II followed by stage III support the unique characteristic of TNBC *i.e.*, involvement of higher grade and stage. Immunomodulatory treatment given in the form of ASBV additionally exerts an immunomodulatory effect and strengthens *Dhatu* (body tissues). TNBC exhibits a higher rate of Tumour infiltrating lymphocytes infiltration within the tumour environment, possibly as a result of somatic mutations that lead to the emergence of neo-antigens and exacerbate the immune response[7]. Thus, ASBV along with ASK and TG were administered as rejuvenation treatment. ASBV contributed to reduce the chances of recurrence or distant spread of the disease, eliminated early and delayed side effects of chemotherapeutic medications,

Table 3 — Evaluation of disease status in TNBC patients treated with Ayurvedic Treatment

Disease Status	Group	Radiological	Clinical	Total
Regression	SR	25 (93%)	02 (7%)	27 (100%)
	SRP	21 (88%)	03 (12 %)	24 (100%)
				51 (75%)
Progression	SR	11(85%)	02 (15%)	13 (100%)
	SRP	04 (100 %)	00 (0%)	04 (100%)
				17 (25%)

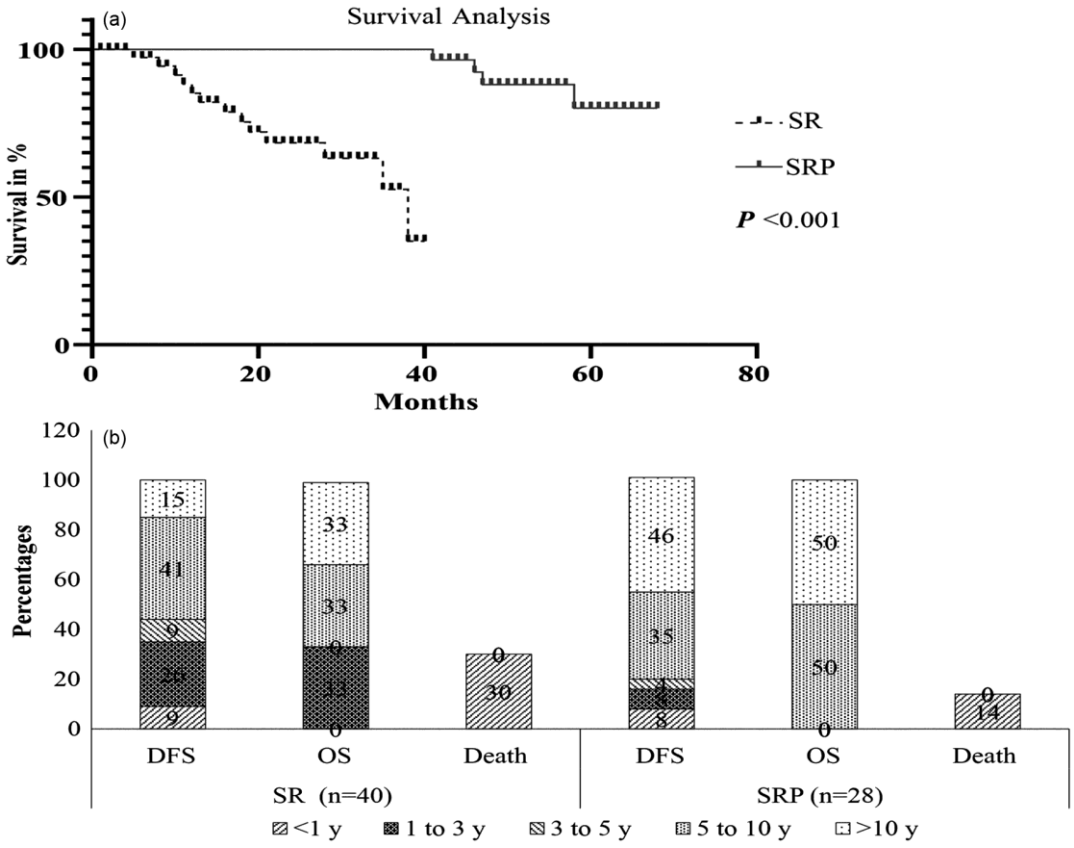

Fig. 4 — Comparative analysis of survival of TNBC patients in SR and SRP groups (a) Kaplan Meier survival analysis. Log Rank (Mantel-Cox) Test considered statistically significant if p-value <0.0001. (b) Disease-free and overall survived as well as expired patients based on the duration (All values are in percentages)

and minimized overall weakness or frailty[8-12]. ASK has immunomodulatory, anti-inflammatory and anti-cancer effect which prevents the further progression of disease by improving immunity[11,13]. TG has also immunomodulatory and anticancer effect[11,14-17].

Shamana chikitsa included MKD[8,10,18], PPV[8,19], AV[20,21] and was for maintaining the equilibrium of *Dosha* and *Dhatu* by improving appetite and digestion, reducing generalized toxicity, imparting anti-inflammatory effects, and improving quality of life. The rationale for the use of these specific medicines and their constituents are depicted in Table 4.

PNK treatment is a comprehensive procedure for detoxification of the entire body, specifically targeting the removal of toxins deeply embedded in all tissues and organs. It is frequently adopted in Ayurvedic therapy and has shown remarkable efficacy[22]. Our hospital team has been recommending PNK as an additional therapy in cancer patients treated with conventional therapy and oral Ayurvedic medicines. We have observed significant improvement in the Quality of Life and overall survival in patients of TNBC, who had received PNK treatment periodically.

Majority of patients in SRP group (n=23, 82%) underwent only *Basti chikitsa*. *Basti* is the superior treatment of *Vatadosha*[23]. It prevents the unwanted growth of cells and helps to prevent the progression of the disease by controlling the vitiated *Vatadosha*. It is

Table 4 — Details of the rationale behind the selection of oral Ayurvedic treatment

No.	Medicines with Dosage	Contents	Rationale behind selection
1	*Atharva Suvarna Bhasmadi Vati* (ASBV) 398 mg with cow's ghee after morning breakfast and after evening snacks with milk	• *Suvarna Bhasma* (Incinerated Gold), • *Mauktik Bhasma* (Incinerated Pearl) • *Guduchi Satva* (Starch preparation of herb – *Tinospora cordifolia* (Willd.) Hook.f. & Thomson)	Immunomodulator, vitality enhancer, possesses detoxifying property, improves appetite and digestion, anti-oxidant activity, pitta pacifying, strengthens the body, eliminates excessive heat and burning sensation, anti-proliferative, anti-cancer activities [8, 15/70; 23/ 72-74] [9,10] [11, 3/8-10] [12].
2	*Kamdudha Vati* (*Mouktikyukta*) [17] 500 mg after morning breakfast and after evening snacks with milk	• *Sudha Varga* (Incinerated conch, pearl, oyster, cowrie, coral) • *Gairik Shuddha* (Purified red ochre) • *Guduchi Sattva* (Starch of *Tinopsora cordifolia* Willd.) Hook.f. & Thomson)	• *Mauktik Bhasma - Pitta* pacifying, Cooling property, Anti toxic Strengthens the body [8,23/72-74] • Anti-ulcer activity [10]
3	*Praval Pishti Vati* (PPV) 500 mg after morning breakfast and after evening snacks with milk	• *Shuddha Praval* (Purified Coral) • *Gulab Jal* (Rose water)	• Alleviates *Tridoshas* • Anti- toxic • Alleviates bleeding disorders • Improves appetite and digestion, thus strengthens the body [8, 23/139-141] • Restrict the aggressiveness of tumor cells [19]
4	*Atharva Shatavari Kalpa* 5 g after morning breakfast and after evening snacks with milk	• *Shatavari* (*Asparagus racemosus* Willd.)	• Increases strength, immunomodulatory. • Improves functions of female genital organs especially of mammary glands and thus, effective in various breast disorders including breast cancer [11, 3/186-188] • Anticancer activity [13]
5	*Aarogyavardhini Vati* (AV) [19, Part 1/448] 500 mg after lunch and dinner with water	• *Kajjali* (Black sulphide of mercury) • *Loha Bhasma* (Incinerated Iron) • *Abhrak Bhasma* (Incinerated Mica) • *Tamra Bhasma* (Incinerated Copper) • *Triphala* • *Shuddha Shilajit* (*Black bitumen purified*) • *Shuddha Guggul* (*Commiphora wightti* (Arn.) Bhandari) • *Kutaki* (*Picrorhiza kurroa Royle* ex Benth)	• Improves appetite and digestion • Alleviates diseases due to vitiated *Medadhatu* [14] • Hepato-protective activity [21]
6	*Triphala Guggul* (TG) 500 mg after lunch and dinner with water [19, Part 2/2423]	• *Triphala* • *Pippali* (*Piper longum* L.), • *Guggulu* (*Commiphora wightti* (Arn.) Bhandari).	• Alleviates *Kapha – Pittadosha*, improves appetite, anti-inflammatory, anti-oxidant, anti-tumor activity by inhibiting the growth and motility of triple-negative breast cancer cells [11, 1/43; 1/55-57; 2/ 39-41], [15-17].

also described as good as 'half treatment' for the *Vatadosha* disorder[23]. Furthermore, it helps eliminate harmful toxins accumulated in the body due to cancer and conventional treatments like chemotherapy and radiation etc. Based on Ayurvedic principles and clinical experience, *Krimi* (worm infestation) is recognized as one of the contributing factors in cancer pathogenesis[24]. *Krimi* hampers the digestive power, leads to poor absorption of food and formation of *Kleda* and *Ama* (undigested matter), thereafter weakens immunity which plays an important role in the aetiology of cancer. To address this, *Krumighna Basti* was administered during the first 7 days of PNK treatment. The protocol included *Krumighna Matra Basti* for first 3 days followed by *Krumighna Niruha Basti* on 4th and 6th day, *Krumighna Anuvasan Basti* on 5th and 7th day, *Erandmooladi Niruha* on 8th,10th and 12th day. Additionally, *Erandmooladi Anuvasana Basti* was administered on the 9th, 11th, 13th, and 14th days. *Erandmooladi Basti*, composed primarily of anti-inflammatory ingredients, is effective in alleviating vitiated *Vatadosha*. This *Basti* was chosen to prevent recurrence and metastasis by controlling the vitiation of *Vatadosha* and reducing inflammatory activity in patients with TNBC, thereby promoting a better prognosis[25].

Vamana, another type of PNK, is the treatment of choice for diseases dominated by *Kapha dosha*[26]. Considering the site of disease, breast or chest region, is *Kaphadosha* dominant region[27]. Also, breast organ/ breastmilk (one of Subordinate tissue of *Rasadhatu* and origin of *Shukravaha srotasa*) is composed of *Rasa, Mamsa, Shukra dhatu* (which have abode and resident relationship-*Ashraya-Ashrayi Sambadha* with *Kaphadosha*)[27-29]. Therefore, *Vamana* may help prevent recurrence or metastases of cancers specifically of *Kapha* dominant organs like the breast[30]. However, due to its intensive nature, *Vamana* is not well-tolerated by all patients and is therefore recommended to a smaller number. For the emesis procedure, a decoction of *Yashtimadhu* (*G. glabra* L.) was used, known for its anti-inflammatory and anti-ulcer properties. *Yashtimadhu* also helps alleviate diseases related to *Vata, Pitta,* and *Raktadosha* (Table 1).

Immunological and metabolic responses have already been studied to a therapeutic course of *Basti* in obesity and documented modulation of immune responses by regulating pro-inflammatory cytokines, immunoglobulins, and functional properties of T-cells. These changes are associated with a reduction in body weight which is maintained even after three months of treatment. The study also documents the safety of the *Basti* procedure[31].

In this study, patient reported outcome data showed significant improvement in the functional score (including physical, role, emotional, social and cognitive functioning), global score of QLQ C30, KPS which indicates the improvement in the health-related QoL in reducing the risk of recurrence or death[32]. Furthermore, significant reduction in symptom score of QLQ C30 in all patients treated with SR and SRP, is suggestive of the efficacy of Ayurvedic treatment to improve the quality of life.

Periodic haematological and biochemical levels were fluctuated within normal limit, showing safety of Ayurvedic treatment. These findings reinforce the therapeutic potential of Ayurveda as a complementary approach in managing TNBC, without compromising patient safety.

ALP represents a collection of membrane proteins anchored by phosphatidylinositol, exhibiting broad substrate specificity. The predictive ability of ALP in relation to bone metastases has been consistently observed, and its biological activity suggests a certain degree of predictability for liver metastases as well. Progressive increase in ALP level can be reported as an important biomarker for detecting metastasis and for differentiation of carcinoma breast with and without metastasis[33]. Hence, significant reduction in ALP levels in the TNBC patients treated with Ayurvedic treatment indicating the effectiveness of Ayurvedic treatment in controlling the disease process.

A significant improvement in haemoglobin levels was seen in TNBC patients in the SRP group. Hb levels are reportedly related to treatment outcomes and survival in patients with breast cancer. The correlation between the anaemia Hb level trajectory during the initial 12-month period following treatment and the poorest 10-year survival rates in breast cancer patients has been studied[34].

The survival analysis demonstrated a statistically significant advantage in survival outcomes for the SRP group (p<0.0001). Additionally, it has been observed the substantial improvement in DFS in the SRP group (46%) compared to the SR group (15%), which implies that patients in the SRP group remained disease-free for longer durations following treatment, potentially indicating enhanced tumor control or delayed recurrence when additional PNK treatment is suggested. The overall survival rate in the

SRP group (50%) was notably higher than in the SR group (33%), suggesting that the SRP regimen may contribute to better long-term outcomes. The percentage of deaths was significantly lower in the SRP group (14%) as compared to the SR group (30%), pointing to an additional survival benefit associated with PNK treatment.

Thus, significant improvement in Hb levels as well as DFS and OS was seen in the patients from the SRP group due to the body detoxifying effect and modulation of metabolic and immune response of PNK. These observations indicate the necessity of periodic PNK with OAM in the treatment of TNBC patients.

This retrospective observational study has several limitations that to be acknowledged. First, the lack of randomization introduces the possibility of selection bias, as treatment allocation was not controlled. Second, reliance on existing medical records may have led to incomplete or inconsistent data, particularly with regard to laboratory parameters, treatment adherence, and long-term outcomes. The study may also be affected by unmeasured confounding variables such as disease stage, comorbidities, and concurrent therapies, which could influence the observed associations. Additionally, variability in OAM treatment protocols, including dosage and duration, may have impacted the results. Given the retrospective nature of data collection, outcome data were not collected prospectively, there may be a lack of uniform criteria for assessing endpoints like quality of life or response rates. These limitations underscore the need for well-designed prospective studies to confirm the efficacy and safety of OAM and PNK interventions across diverse cancer populations.

Conclusion

The aggressive nature of TNBC, marked by a high tendency for relapse, distant metastasis, poor prognosis, and chemoresistance, along with inflammatory molecules reducing immune response, underscores the need for more effective treatment strategies. Specifically, Ayurvedic treatments involving *Shamana* and *Rasayana* therapies, combined with PNK, have proven to be highly effective in increasing both DFS and OS. The integration of adjunct Ayurvedic treatment has demonstrated significant benefits in improving the QoL and survival outcomes for TNBC patients. These findings highlight the necessity of incorporating periodic PNK along with OAM in the treatment of TNBC to prevent recurrence and metastasis, offering a promising complementary approach to conventional cancer care. This retrospective finding provides a strong foundation for prospective studies to evaluate the efficacy of OAM and PNK in various types of cancer, with the goal of improving patient survival and quality of life.

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Conflict of Interest

Atharva Suvarna Bhasmadi vati, *Mauktik Kamdudha vati*, *Praval pishti vati* are included in the "A pharmaceutical kit" published Indian Patent (application no. 201921018276), International Patent PCT/IB2020/051120 and US Patent no. 17/609,673 for reducing side-effects of chemotherapy.

Author Contributions

The present study was conceptualised and designed by SPS, VVD, TVP and AVK. The data was analysed by VRG, SSS, SRG. The resources were provided by VVD, SPS, SNG, VRG, SJK, SMD, SRG and executed by SJK, BSS, NSS, VSA, DRD, ASS, SKS, VAR, STD, AAD, AAS AYS. The study was supervised by VVD, VSG. Original draft was written by VSG, BSS and reviewed and edited by SBC, SSS, VVD, VSG and all the rest of the authors had read and approved the manuscript.

Ethics Approval

The present study was approved by Institutional Ethics Committee of Bharatiya Sanskriti Darshan Trust, Wagholi, Pune held on 04 August 2006.

Informed Consent

A written informed consent was taken from every patient before commencement of the study.

Data Availability

The dataset generated during this study is available from the corresponding author upon reasonable request. It is not publicly accessible due to privacy and ethical considerations involving human participants.

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