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Development of transdermal patch from *balaa* root (*Sida cordifolia* Linn.)extract

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ABSTRACT: *Balaa,* is popular for analgesic properties and anti-inflammatory actions in ayurvedic medicine. The transdermal patch was developed as a novel drug delivery system to improve the bioavailability and patient compliance of traditional medicines. *Balaa-moola kwatha* was prepared as per the reference from *Sarngadhara samhita* for the need of extract. Thus prepared *kwatha* was used to develop transdermal patch. The patches were prepared using the solvent casting method, and their physicochemical properties such as thickness, weight, tensile strength and drug content were evaluated. The study highlights the importance of novel drug delivery systems in improving the efficacy of traditional ayurvedic medicines. The transdermal patch of *balaa* (*Sida cordifolia* Linn) root extract offers a safe and effective mode of administering the medicine, improving patient compliance and reducing the frequency of administration. This research demonstrates the potential of using traditional medicines in modern drug delivery systems to improve patient care. Here such medication could be made with the standards that might be made use in emergency management.

Keywords: *Sida cordifolia,* Linn, transdermal patch, anti-inflammatory, solvent casting method

INTRODUCTION

The emergence of new technologies provides unique opportunities to exploit novel approaches in drug delivery. A shift from conventional drug delivery system to novel drug delivery system has noticed a drastic change in pharmaceutics.The first commercially available prescription patch was approved by the U.S Food and Drug Administrationin in December 1979.[1]These patches administer scopolamine for motion sickness. Transdermal Drug Delivery System (TDDS) is defined as self-contained, discrete dosage forms which when applied to intact skin deliver the drug through the skin at a controlled rate to systemic circulation. The rate or dose controlled drug delivery system results in constant and continuous output, predicted and extended duration of action, lesser side effects. The wind of change in the drug scenario is blowing forcefully worldwide.[2]

Sida cordifolia has the chemical constituents such as ephedrine, psuedoephidrine, sterculic, malvalic and coronaric acids, fatty acids, saponine, betaphenethylamine, hypaphorine, ecdysterone, indole alkaloids, palmitic, stearic and and β– sitosterol. Regarding the therapeutic uses *balaa* is alternative tonic, astringent, emollient and aphrodisiac. Parts are used for following purposes:

- Bark - considered as cooling. It is useful in blood, throat, urinary system related troubles, piles, phthisis, insanity etc.
- Seeds- The seeds as considered as aphrodisiac.
- Roots -It is regarded as cooling, astringent, stomachic and tonic, aromatic, bitter and diuretic.

In *ayurveda* many dosage forms are described, but as per the current trend we can modify the ancient dosage forms into newer one. Here it is an attempt to prepare transdermal patch from *balaa* (*Sidacordifolia*Linn.) root extract. The herb *balaa* (*Sida cordifolia* Linn.) has got many therapeutic importance[3] like, *vedanaasthaapana*, *sothahara*, etc. Regular preparation of *kashaaya* is not patient friendly. So we have to find an alternate way. Keeping this aspect in view, study has been undertaken to prepare transdermal patch of *balaa*-root extract and to evaluate the analytic profile of the prepared patch.

***Balaa* (*Sida cordifolia,* Linn.)[4]**

Sida cordifolia is a small, erect, downy shrub. The leaves of the plant are chordate-oblong or ovate-oblong and fruits with a pair of awns on each carpel. Roots of the plant which constitute a drug are 5-15 cm long with few lateral roots of smaller size. The tap roots are generally branched at the tip. The outer surface of the root is off to greyish yellow. It is almost odourless with slightly bitter taste (Rangari et al., 1995). The present review highlights the contribution of *Sida cordifolia* in modern system of herbal medicine for new drug development. There is correlation established between the active constituents and their uses in different diseases.

Botanical description

Sida cordifolia grows well through the plains of India, especially, in damp climates. The shrub grows up to 0.75 - 1.5 meters in height. The root and the stem are stout and strong. The leaves are 2.5-7cm long and 2.5-5 cm broad, with 7-9 veins. They are heart shaped, serrate and truncate. The flowers are small, yellow or white in colour, solitary and axillaries. The fruits are moong-sized, 6-8 mm in diameter. The seeds are called as *bijabanda* in *ayurveda*, are greyish black in colour and smooth. The plant flowers from August to December and fruiting occurs from October to January (Pole et al., 2006).

***Sida cordifolia*- physiological effects**

- It has a depressant rather than a stimulant effect on the central nervous system
- May decrease both blood pressure and heart rate
- Has a hypoglycemic (blood sugar lowering effect)
- No real evidence to support its use as a weight loss supplement
- Increases pain tolerance
- Has an anti-inflammatory effect
- Possible antioxidant effect

Figure1 *Balaa-moola coorna*

Materials and methods

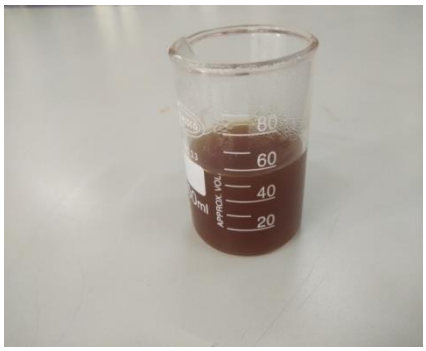
Balaa root (*Sida cordifolia* Linn.) was purchased from authentic sources locally and the chemicals like HPMC (Hydroxypropyl methyl cellulose), DBP (Dibutyl phthalate) and glycerine were also procured. The equipments were desiccators, digital Vernier caliper,electronic balance,digital pH meter, transdiffusion cells, magnetic stirrer, petri-dish, glass utensils, hot water bath and tray dryer.

Figure 2 *Balaamoola kwatha* preparation

Preparation of *Balaa* root extract:

Figure 3 *Balaa-moola corona*

Figure 4 *Balaamoola kwatha*



In *ayurveda*, many extraction methods are explained like *swarasa, kwaatha, hima, phanta, arka* etc. All of these preparations are considered as aqueous extractions. For the present study *kwaatha* method was used.[5]

Table No.1

Sl.No.	**Ingredients**	**Quantity**
01	*Balaa-moola* (*Sida cordifolia* Linn.) *kwaatha-coorna*	20 g
02	Water	160 ml

Heated on *mandaagni* and reduced to 1/4th,then filtered to get *balaa-moola kwaatha* of 40 ml.

Preparation of transdermal patch[6]

Methodof preparation of membrane of matrix type of transdermal patch

- Transdermal patches of *Sida cordifolia Linn.* root extract were made by the evaporation casting method.
- The chosen combination is HPMC and DBP was used as a permeation enhancer.
- 1000 mg HPMC was dissolved in 15 ml of ethanol and 1 ml of DBP and 1 ml of glycerine using a magnetic stirrer with Teflon coated magnetic bead. The stirring was continued for 3hrs at 300 rpm/min to get clear homogenous polymer solution.
- Then added 2g of *Balaa* root extract to the solution, and the mixture was homogenized again in the magnetic stirrer for 1hr.
- The resulted solution was poured into glycerine polished petri-dish and dried at room temperature for 24hrs.
- On completion of mentioned time, dried-outpatches were isolated from petri-dish and kept in desiccators for further examinations.
- Three membranes were prepared in the same proportion and done with all the possible physico-chemical parameters. By this method six patches were prepared at once . Among these 6 patches 3 were used for the tests such as Folding endurance, Tensile strength test.

Figure 5 Concentration of Balaa root extract

Analytical study

Raw material *balaa* root and prepared extract were subjected to analytical parameters like organoleptic characters, physico-chemical parameters and the preliminary phytochemical analysis of *balaa* root extract(*kwaatha*), as per API standards.[7]

Physicochemical evaluation of transdermal patch

Development of controlled release transdermal dosage form is a complex process involving extensive research. Transdermal patches have been developed to improve clinical efficacy of the drug and to enhance patient compliance by delivering smaller amount of drug at a predetermined rate. This makes evaluation studies even more important in order to ensure their desired performance and reproducibility under the specified environmental conditions.These studies are predictive of transdermal dosage forms and can be classified into different types including physicochemical evaluation, in-vitro evaluation etc.

Formulated patches were subjected to the preliminary evaluation tests. Patches with any imperfections, entrapped air, or differing in thickness, weight(or)content uniformity were excluded from further studies.

Uniformity of weight

This was done by weighing different patches of individual batch taking the uniform size atrandom and calculating the average weight of three. The tests were performed on patch which was dried at60˚C for 4 hrs. prior to the testing

Thickness of the patch

The thickness of the patch was assessed by using digital Vernier caliper at different points ofthe patch. From each formulation three randomly selected patches were used.The average value for thickness of a single patch was determined.

Drug content determination

The patches were taken and added to a beaker containing 100 ml of distilled water. The medium was stirred magnetic bead for5 hrs. The solution was later analyzed through pH meter.

Folding endurance

This was determined by repeatedly folding one patch at the same place till it broke. The number of times the patch could be folded at the same place without breaking gave the value of folding endurance.

Percentage moisture content

The patch were weighed and kept in desiccators containing calcium chloride. After 24hrs. the patches were taken out and weighed. The percentage moisture content was calculated using the following formula.

$$\text{Percentage moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

Percent elongation

When stress is applied, a patch sample stretches and this is referred to as strain. Strain is basically the deformation of patch divided by original dimension of the sample.

Generally elongation of patch increases as the plasticizer content increases. It is calculated by using the following formula.

$$\text{Percentage elongation} = \frac{\text{Increase in length of patch}}{\text{Initial length of patch}} \times 100$$

Tensile strength

Tensile strength is the maximum stress applied to a point at which the patch specimen breaks.

It is calculated by the applied load at rupture divided by the cross- sectional area of the strip as given in the equation below

$$\text{Percentage elongation} = \frac{\text{Load at failure}}{\text{Patch thickness} \times \text{Patch width}} \times 100$$

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Figure 6 Magnetic stirrer

RESULTS

Appreciating results were observed. As the drug *balaa* is easily available and the extraction method is also easy. Preparation was in *kwatha* form for the present study. Raw material *balaa* root/root extract and prepared extract membrane were subjected for physico chemical analysis. All the parameters like organoleptoc characters, physico chemical parameters are tabulated as follows

Table No.2
Organoleptic characters of *balaa root*

Sl.No.	**Organoleptic characters**	
01	Colour	Brown
02	Taste	Characteristic
03	Odour	Characteristic

Table No.3
Physico-chemical parameters of *balaa- root*

Sl.No.	**Parameter**	**Result**
01	Foreign matter	Nil
02	Ash value	4.343%
03	Acid insoluble ash	0.434%
04	Water soluble extractives	7.220%
05	Alcohol soluble extractives	1.896%

Table No. 4
Organoleptic characters of *bala root* extract (*kwaatha)*

Sl.No.	**Organoleptic characters**	
01	Form	Liquid
02	Colour	Brown
03	Taste	Tasteless
04	Odour	Characteristic

Table No.5
Physico-chemical parameters of *balaa root* extract (*kwaatha*)

Sl.No.	**Parameter**	**Result**
01	Specific gravity	1.005
02	pH	5.67
03	Total solids	1.166 %

Table No. 6
Preliminary phytochemical screening of *balaa root* extract (*kwaatha*)

SL.NO.	**Test**	**Result**
01	Carbohydrates	Positive
02	Reducing sugar	Positive
03	Monosaccharide	Positive
04	Pentose sugar	Negative
05	Hexose sugar	Positive
06	Non-Reducing sugar	Positive
07	Proteins	Negative
08	Amino acids	Positive
09	Steroids	Negative
10	Flavonoids	Positive
11	Alkaloids	Negative
12	Tannins	Positive
13	Cardiac glycosides	Negative
14	Anthraquinone glycosides	Negative
15	Saponin glycosides	Positive

Table No. 7
Organoleptic characters of *balaa root* extract membrane

Sl.No.	**Organoleptic characters**	
01	Colour	Brown
02	Odour	Characteristic
03	Texture	Soft & Smooth
04	Nature	Translucent

Figure 7 Transdermal membrane

Table No. 8
Physical properties of *balaa root* extract membrane

Sl.No.	**Parameter**	**Observation**
01	Specimen type	Flat
02	Initial width	10 mm
03	Initial thickness	0.3 mm
04	Initial Gauge length	50 mm
05	Initial area	3 mm^2
06	Speed of loaded machine	2 mm/min
07	Final diameter	0 mm
08	Final Gauge length	53.79 mm
09	Final area	0 mm^2
10	Load cell	5 kn
11	Area under curve	0.04 mm^2
12	% Reduction area	100
13	% Elongation	7.58
14	Tensile load	14.03 N
15	Tensile strength	4.68 Mpa
16	Young's Modulus	61.714 Mpa

Discussion

The study was planned to formulate matrix type of transdermal patches and thus prepared membrane of matrix type of TD patches.The polymer was chosen after optimization of polymer with permeation enhancer. HPMC was showed more satisfying features compared to other polymers. In optimization the patches were prepared and performed physical characterization of the patches. HPMC was used as polymer.Organoleptic characters were observed as colourless and clear, thin,characteristic odour and transparent in texture. Solvent casting method was selected because of its conveniences. This method will help to avoid fast evaporation of the dope solution by the presence of inverted funnel.The drying of the patches was done at room temperature for 24-48 hrs of time duration.

Conclusion:

The transdermal drug delivery system is one among the most effective drug dosage form.*Balaa* is having importance in traditionally and medicinally. *Balaa (Sida cordifolia Linn.)* is one among the *dasamoolas(*very popular ten root drugs *),* so *balaamoola* is used for the present study. After many trials able to prepare transdermal patch from *balaa* root extract. The selected proportion of the TD patch membrane is1000mg of HPMC, 1 ml of DBP, 1 ml of glycerine and 2g of *balaa-moola kwaatha*. The formulated membranes satisfied all the features of an ideal product (Organoleptic, physical parameters ,etc.) as the plan was to prepare transdermal patch for sports injury to relieve the acute inflammation readily. Thus completed the preparation part and drug standardization parts. The anti inflammatory activity(preclinical and clinical)of *balaa-moola* extract-patch can be considered as scope for the further study.

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