Transdermal Contraceptive System: Clinical Management

By Lee P. Shulman, MD [2]

Disclosure Declaration

• Grant Support

• Honoraria and consultation fees

• Participation in company sponsored speakers’ bureau
Presentation Outline

• How to use the contraceptive patch
  – Starting patients
  – Managing patients

• Counsel women about appropriate contraceptive options
Composition of Patch

- Backing layer
- Middle layer
- Release liner

Composition of Patch
Where to Apply the Patch

- Clean, dry, intact healthy skin
  - Buttock
  - Abdomen
  - Upper outer arm
  - Upper torso
  - In a place
First Day Start or Sunday Start

For First Day Start: the patient should apply her first patch during the first 24 hours of her period. If therapy starts after Day 1 of the menstrual cycle, a nonhormonal contraceptive (such as a condom or diaphragm) should be used concurrently for the first 7 consecutive days of the first treatment cycle.

OR

For Sunday Start: the patient should apply her first patch on the first Sunday after her period starts. She must use backup contraception for the first week of her first cycle only. If the menstrual period begins on a Sunday, the first patch should be applied on that day. No backup contraception is needed.
Weeks 2 and 3

A new patch is applied on Week Two (Day 8) and again on Week Three (Day 15), on the usual “Patch Change Day.” Patch changes may occur at any time on the Change Day. Consecutive patches should be applied to a new spot on the skin to help avoid potential irritation, although they may be kept within the same anatomic site.
Patch-free Week

Week Four is patch-free (Day 22 through Day 28), thus completing the four-week contraceptive cycle. Bleeding is expected during this time.
Rationale for no Placebo Patch

Why is there no placebo patch?

• Most important reason is to avoid potential confusion
• Because a new patch is applied each week for 3 weeks, pregnancy could result if placebo patch was mistakenly worn in middle of the cycle
• Patch Change Day is same activity every week
• In clinical trials, participants did not express need for placebo patch
Next 4-week Cycle

The next four-week cycle is started by applying a new patch on the usual “Patch Change Day,” the day after Day 28, no matter when the menstrual period begins or ends.

Under no circumstances should there be more than a 7-day patch-free interval between dosing cycles.
Adhesion

Patch adhesion was assessed indirectly by replacement rates for complete and partial patch detachment

- More than 70,000 patches worn
- Results (6-13 cycles) showed that 4.7% of patches were replaced because they either fell off (1.8%) or were partly detached (2.9%)
- Similarly, in a small study of patch wear under conditions of physical exertion and variable temperature and humidity, only one patch was replaced
Patch Replacement Rates for Complete and Partial Detachment

Partial (2.9%)
70,552 total patches worn in pooled clinical trials

Complete (1.8%)
Patch Replacement Rates in Warm Humid Climates

Partial (2.6%)

4,877 total patches worn in Florida, Georgia, Louisiana

Complete (1.7%)
Patch Replacement Rates in Exercise Study

87 total patches
Activities: cool water immersion, sauna, treadmill, whirlpool
Complete (1.1%)

No partial detachment rates (0%) were reported in this study
Partial or Complete Detachment

<24 hours

>24 hours

or uncertain

Attempt
Reattachment

Unsuccessful

Successful

Continue
method as
usual

Apply new
patch. Change
day remains the
same

Stop current
cycle. Start new
cycle by
applying new
patch

Use backup
c contraception for
one week

Forgot to Apply/Change Patch
(in any Patch Cycle)

Week 1

• Apply patch as
  soon as
  remembered

• Must use
  backup
  contraception
  for 1st week of
  new cycle

Week 2 or Week 3

>48 hours

<48 hours
• Remove current patch
• Apply new Patch immediately
• Must use backup contraception for one week
• Remove current patch
• Apply new Patch immediately
• No backup contraception needed

Week 4

• Remove patch when remembered
• No backup contraception required
Change Day Adjustment

If patient wishes to move Patch Change Day she should:

• Complete current cycle
• Remove the third patch on the correct day
• During the patch-free week, a new Patch Change Day may be selected by applying a new patch on the desired day of week
• In no case should there be more than 7 consecutive patch-free days
Transdermal Contraceptive System:
Clinical Management

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Switching From OC

• Apply patch on 1st day of withdrawal bleeding
• If no withdrawal bleeding within 5 days of the last active (hormone-containing) pill, pregnancy must be ruled out prior to start of patch
• If starting patch after the first day of withdrawal bleeding, a non-hormonal contraceptive should be used concurrently for 7 days
• If more than 7 days elapse after taking the last active pill, patient may have ovulated
• Patient should consult clinician before initiating treatment with patch
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Switching From IUD

- Apply patch on any day prior to or on the scheduled IUD replacement day
- If patch commencement occurs after IUD removal, rule out pregnancy and begin transdermal system using a barrier method for the first week of the first cycle.
Switching From Injectables

• Apply patch on any day prior to or on the scheduled reinjection (DMPA; MPA/E2C) day
• If patch commencement occurs after scheduled reinjection, rule out pregnancy and begin transdermal system using a barrier method for the first week of the first cycle.
• Pre-filled MPA/E2C syringe?
Switching From Patch

- If patch has been used correctly, patient may begin new method without need for pregnancy assessment (unless symptoms/presentation direct such evaluation)
- Commencing new method will depend on particular method
- If patch has not been used properly, evaluate woman for pregnancy before starting new method
Most Common Adverse Events:
Comparative Data

Breakthrough Bleeding or Spotting

- Treatment should be continued
- Usually disappears after the first few cycles
- If BTB persists, a cause other than patch should be considered
- Incidence of BTB with patch is statistically and clinically comparable to that seen with 35µg EE/NGM and EE/Tri LNG

If breakthrough bleeding or spotting occurs during patch usage:
Comparative Data: Subjects With Breakthrough Bleeding and/or Spotting


p < 0.001 at cycle 1
Absence of Withdrawal Bleeding

- Treatment should be continued on the next scheduled Change Day
- If used correctly, absence of withdrawal bleeding is not necessarily an indication of pregnancy
- Possibility of pregnancy should be ruled out if absence of withdrawal bleeding occurs in 2 consecutive cycles

In the event of no withdrawal bleeding (bleeding that should occur during the patch-free week):
Anticipatory Counseling: Breast Symptoms

• As with all hormonal methods, appropriate patient counseling should take place.
• Counseling women about possible side effects will help with expectations and will promote correct and consistent use.
• With contraceptive patch, breast tenderness was higher than an OC comparator only in cycles 1 and 2, and there was no difference in cycles 3-13. Discontinuation due to breast tenderness was only 1%
Comparative Data for Breast Symptoms by Cycle
For cycles 1 & 2, P < 0.001 and for cycles 3 –13, p > 0.10
Severity of Breast Symptoms:
Combined Data

Body Weight and Pregnancy

- 15 total pregnancies
  - 5 among 83 subjects with body weight .90 kg (3% of study population)
  - 10 among 3,236 subjects with body weight .90 kg were uniformly distributed

- For women at or above 198 lbs, consider the patient’s individual needs when choosing a contraceptive
Hormonal Contraception and Weight

• Progestin-only pills: Increased pregnancy rates in women of higher body weights1
• Norplant®: Cumulative five-year pregnancy rates are higher in women of greater body weights2
• Findings in recent NICHD-sponsored study report increased OC failure in women with higher body weights3

2 NORPLANT® (levonorgestrel implants) System (PI)
Women > 198 lbs: Recommendations

• The decision about which contraceptive method to use is one that should be made by the woman and her health care professional
• For women at or above 198 lbs., patients should be counseled appropriately
• Patient’s individual needs should be considered when choosing a contraceptive
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Percentage of Pregnancies at 1 year
Typical Use with Other Methods

Contraceptive Method % Pregnant at 1 year

Spermicides 26%
Periodic abstinence 25%
Cervical cap 40%(parous), 20%(nulliparity)
Sponge 40%(parous), 20%(nulliparity)
Diaphragm 20%
Condom 14%(male), 21%(female)
Precautions

• Body weight 198 lbs. (90kg)
• Physical examination and follow-up
• Lipid disorders
• Liver function
• Fluid retention
• Emotional disorders
• Contact lenses
• Drug interactions

• Interactions with laboratory tests
• Carcinogenesis, mutagenesis, impairment of fertility
• Pregnancy
• Nursing mothers
• Pediatric Use
• Geriatric use
• Sexually transmitted diseases
• Patch adhesion
Drug Interactions

• Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids
  - Barbiturates, griseofulvin, rifampin, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, St. John’s Wart, and possibly with ampicillin

• Pharmacokinetic study with contraceptive patch showed no significant interaction with tetracycline

*Refer to full Prescribing Information for full list of drug interactions
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Tetracycline Study: NGMN Results
Presentation Outline

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Tetracycline Study: EE Results
How do you choose a method for your patient?

You Don’t!

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Elicit and Respect Patient Choice

- Patient priorities may direct choice
- Recognize your possible biases
- Any one unique advantage of one method relative to others may be critical
- Patient needs often differ over time
- Preferred method at age 20 may not be optimal choice at age 30 or age 40
Considerations in Choice of Birth Control Methods

- Effectiveness
- Incidence of side effects
- Convenience
- Desired duration of contraception (ie, future childbearing plans)
- Reversibility
- Noncontraceptive benefits
- Cost
- STI prevention
Patient Management Conclusions

• Impossible to predetermine patients contraceptive needs and/or desires
• A menu of options should be presented to all appropriate women
• With good counseling, women will select a method that best suits their respective contraceptive needs
Contraceptive Patch Summary

• New, novel method appropriate for a broad range of women
• Shown to have comparable efficacy and safety to OC’s
• Once-a-week dosing resulted in statistically better compliance than with OC comparator
• Side effects were generally mild and transient
• Can be worn on several areas of the body - most typically the lower abdomen or buttocks
• Adheres well to the skin, allowing women to perform activities like bathing, swimming, and exercising

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http://www.diagnosticimaging.com/tutorial/transdermal-contraceptive-system-clinical-management-1

Links: