

Effective Anticoagulation Self-Management In A Diverse Population of Oral Anticoagulation Patients Using The Protime System

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BACKGROUND

- Oral anticoagulant therapy (OAT) requires the use of pharmaceuticals known to have a “narrow therapeutic index” requiring close monitoring to be both safe and effective.
- There is a known relationship between the maintenance of the therapeutic range and a reduction in adverse events.
- Maintenance of the therapeutic range is improved with more frequent testing.
- Patient self-testing (PST) has become an accepted method for monitoring patients on long-term OAT allowing patients greater access to more frequent testing.
- In some clinical settings (e.g. Germany, The Netherlands) the extension of the use of PST, to patient self-management (PSM) allows patients to adjust their own therapy based on defined clinical algorithms.

METHODS

- Identify and select patients (N=56) with a history of compliant PST based OAT management.
- All patients were trained using the ProTime® Microcoagulation System.
- Patients were divided to either remain as PST (N=30) or transition to PSM (N=26).
 - PSM patients were supplied with a dosing algorithm, depending on their target INR range.
 - Dosing was based on the use of an Expanded Therapeutic Range in which the INR is allowed to vary beyond the nominal therapeutic range provided testing frequency is increased.
- Evaluate the performance of these patients over a period of 12 months by a comparison of time in therapeutic range (TIR) and number of dose adjustments while managed through PSM to:
 - TIR and dose adjustments of a comparable PST group.
 - Historical TIR and dose adjustments for PSM patients when they were managed as PST.

Example dosing algorithm

| INR | Action | Dose |
|--|---------------------------------|---|
| 4.0 and above | Call clinic | Await instruction |
| 3.5-4.0 High | Repeat test Must change dose | Decrease dose by 1/2 tablet every other day recheck in 3-4 days |
| 3.0-3.5 Acceptable range for high frequency testers | May change dose | If no dose change recheck in 3-7 days If dose change see above |
| 2.0-3.0 Prescribed Range | No change | Continue dose |
| 1.5-2.0 Acceptable range for high frequency testers | May change dose | If no dose change recheck in 3-7 days If dose change see below |
| 1.0-1.5 Low | Repeat test Must change dose | Increase dose by 1/2 tablet every other day recheck in 3-4 days |
| 1.0 and below | Call clinic | Await instruction |

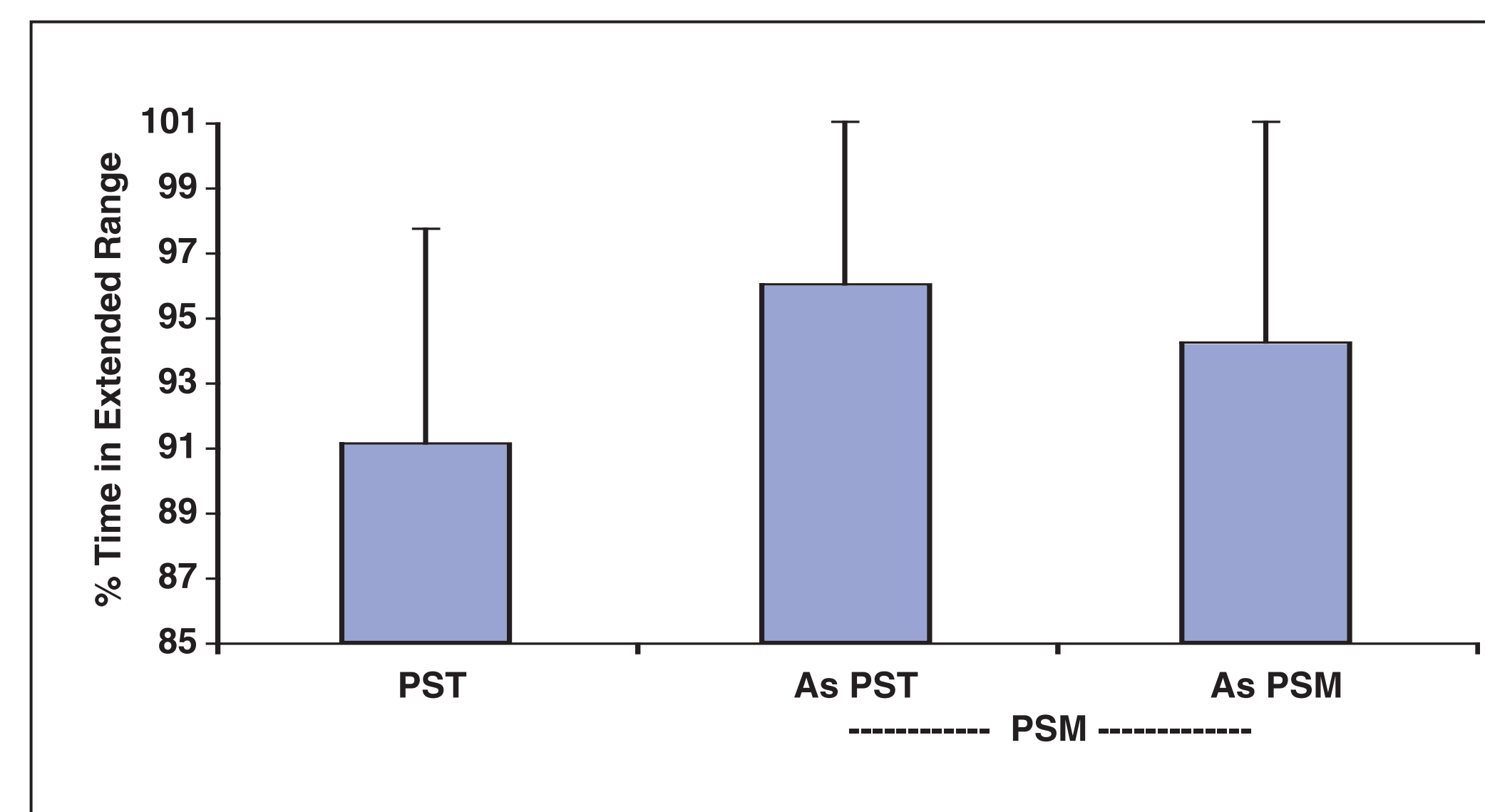
If dose change is needed

You should have two INR readings from the same color group before you change your dose-this is 2 similar readings from one testing session.

When changing your dose, record the date of the dose change on the dose log. Use the line on the dose log that is the same as your new dose.

RESULTS

Time in Extended Therapeutic Range

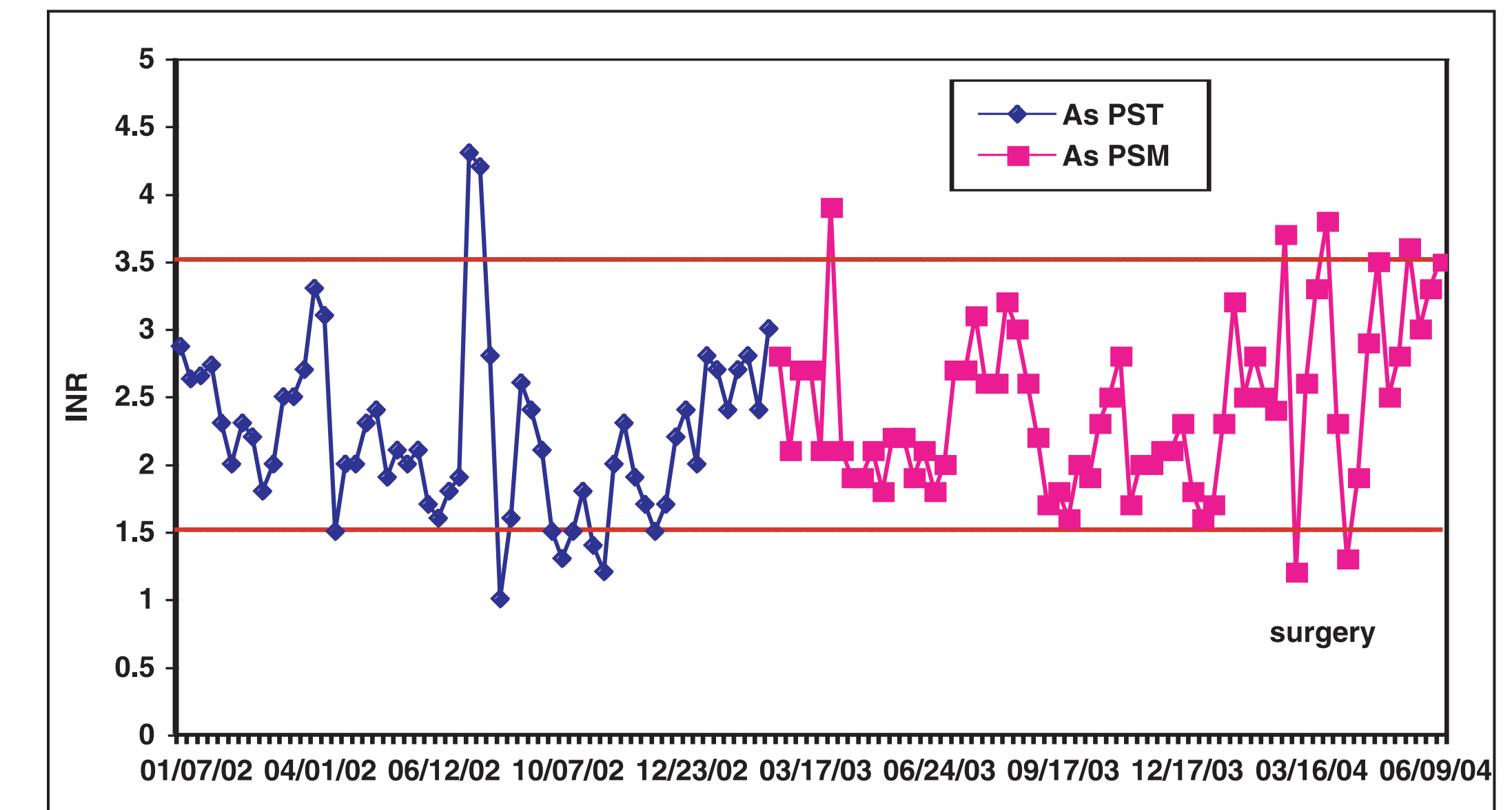


| Time in Extended Therapeutic Range | | | | | p | |
|------------------------------------|--------|------|------|-----|-------|----|
| | | Mean | Min | Max | | |
| PST (N=30) | | 91.1 | 74.3 | 100 | 0.003 | NS |
| PSM (N=26) | As PST | 96.0 | 82.9 | 100 | | |
| | As PSM | 94.2 | 70.1 | 100 | | |

Patients maintained the TIR at a high level (average >90%) when employing the extended therapeutic range.

There was no statistical difference between the % time in range for the PSM group while self-managing compared to either their historical PST performance or the control PST group.

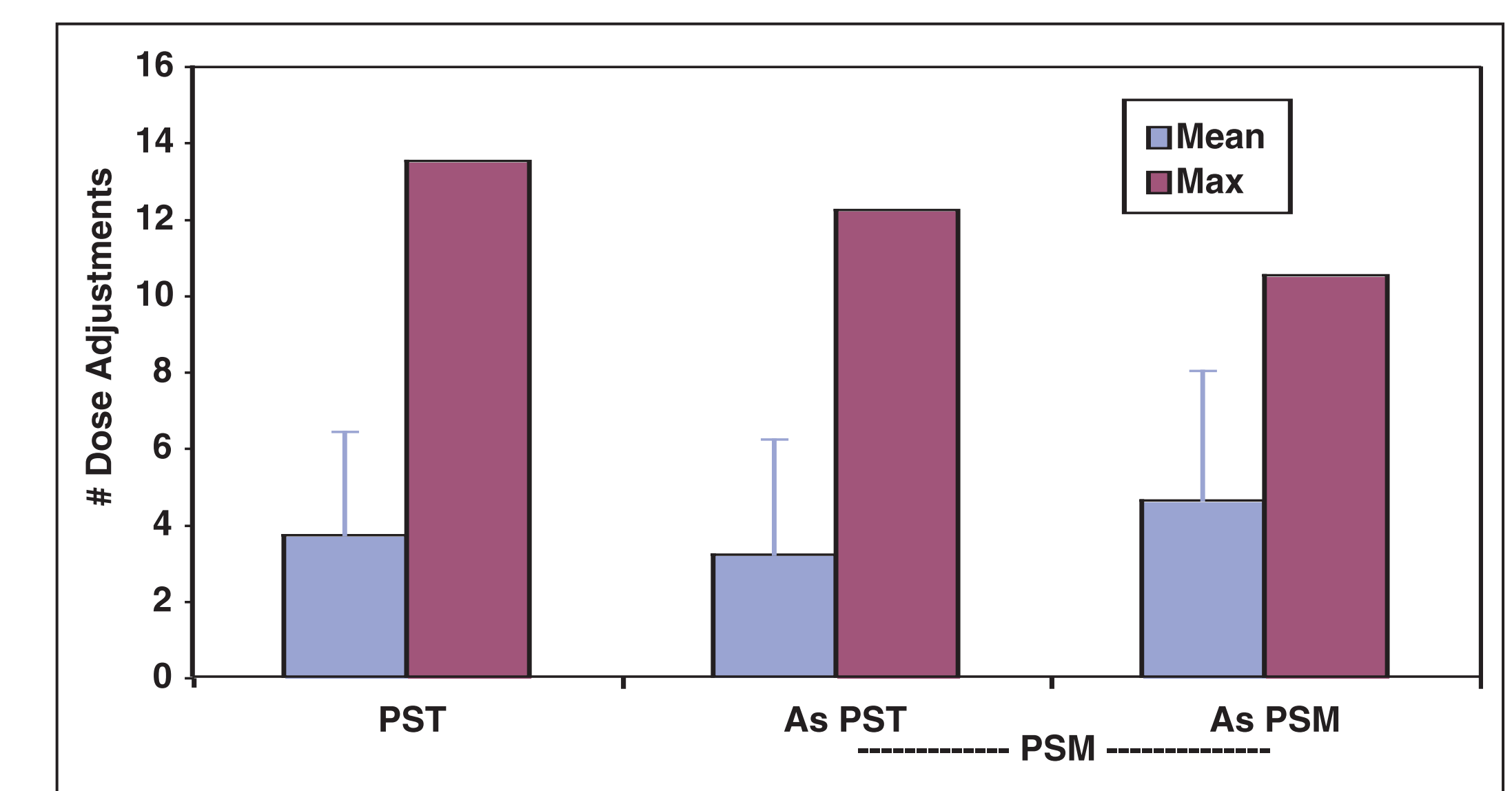
Timecourse for a Typical PSM Patient



INR results from home testing as a PST patient (♦) and as a PSM patient (◻). Red bars indicate expanded therapeutic range.

Patient discontinued OAT briefly in March 2004 for a surgical procedure as indicated by “surgery” on chart above.

Dose Adjustments Per Year



“There was no statistical difference between the average number of dose changes for the PSM group while self-managing compared to either their historical PST performance or the control PST group.”

CONCLUSION

- Patients who have demonstrated proficiency and compliance in a PST program can be successfully transitioned to PSM.
- Following this transition, the patients are capable of maintaining their TIR at a level comparable to that observed while managed by PST.
- These patients gain an added level of independence from the clinic, requiring less frequent visits and telephone contact.