Assessment of Clinical Outcomes of a Pharmacist Managed Anticoagulation Clinic in a Malaysian Tertiary Hospital

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PODIUM SESSION II: CLINICAL OUTCOMES STUDIES
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Warfarin Therapy

- Warfarin - most widely used vitamin K antagonists (VKAs) worldwide in the prevention and treatment of blood clots. It’s use is complicated by various factors.
  

- Utilizing the correct intensity and maintaining the patient in the therapeutic range – determinant of its therapeutic effectiveness and safety.
  

- 3 primary models available for managing oral anticoagulant care are Usual medical care, Anticoagulation clinic, Patient self management
  
  Wilson SJ. et al. 2003
• Anticoagulation management services (AMSSs) (ie; anticoagulation clinics) is accepted as gold standard and one of the approaches to improve anti-coagulant care.

  Ansell J et al. 2001

• Pharmacist managed AMS in comparison to other clinics (physician/nurses):
  - achieved superior anticoagulation control
  - favourable impact on hospitalization

  Ruud KM. et al. 2010
Pharmacist Managed AC

- Pharmacist - staffed ACs provided patient education, a more consistent monitoring and early recognition of risk factors.

  Chamberlain MA. et al. 2001

- Pharmacist-managed AC service demonstrated decreased adverse events (39-47% bleeding) and reduced hospital costs (USD 375-1620 per patient).

  Saokaew S. 2010, You JHS CA. et al. 2008
• Payers are also the provider of the healthcare system in Malaysia.

• Allocation of additional resources for establishing or expanding AC services is a significant concern.

• The clinical effectiveness of a local clinic setting is not available currently.
Research Questions

• Is the pharmacist managed anticoagulation clinic more effective than the usual medical care in Kuala Lumpur Hospital (KLH)?
Objectives

- To compare the anticoagulation control between the clinics in terms of:
  - % of INR values as percent-time in range
  - % of hemorrhagic or thromboembolic events
  - average clinic visits
Significance of Study

• Expected output from the research

Clinical outcomes of PMAC

Data obtained serves as **benchmark in providing local data** in PMAC

We hypothesize that pharmacist managed anticoagulation clinic has better clinical outcomes.
RESEARCH METHODOLOGY
Study Design

Chronic Warfarin Therapy

Usual Medical Clinic

Pharmacist Managed Anticoagulation Clinic

Systematic Random Sampling

Data Collected using a Data Collection Form:
- Demographic
- % of time INR within target range
- Clinical/Adverse Outcomes

A 6 month Retrospective Cohort Study of the effectiveness of the 2 models of anticoagulation care.
Study Location:

A 2302 bedded government tertiary referral hospital in Malaysia – Kuala Lumpur Hospital

- Performed June 2011- February 2012
- Follow up period 2008 - 2012
The usual medical care (UMC)
- rotational medical officer-physician managed usual medical clinic is conducted 3 days in a week.

Pharmacist managed Anticoagulation Clinic (PMAC)
- Pharmacist Managed Warfarin Medication Therapy Adherence Clinic (WMTAC) is conducted a day in a week.
• Data Collection:

• The descriptives, INRs and adverse events details for each patient was collected using a data collection form. *e.g. Data Collection Form Sample. DCF*

• All subjects were grouped into UMC and PMAC.

• Data analysis was performed using patients’ samples. *e.g. SPSS Version 17*
## Inclusion / Exclusion Criteria

### Inclusion Criteria

Patients were included in the study if they:
- are 18 years and above;
- are currently on warfarin therapy;
- were managed for at least 6 months by the usual medical care or the PMAC.

### Exclusion Criteria

Patients were excluded if:
- their warfarin indication is anti-phospholipid syndrome or;
- they were managed less than 6 months by the usual medical care or the PMAC.

Both of which has an increased risk of complications.

Schulman S. et al. 2008
Non-controlled studies - physician clinics achieve 50% control, whereas AC achieves a 10% increase to 60% control which is clinically important.

Wilson SJ. et al. 2003

As for clinical difference of 10%, a sample size of about 120 patients per group would be needed for standard deviation of 0.25 between the groups and statistical power of 80% with an α error of 5% to detect the difference.

nQuery 2009 (Stat. Sols.) Software
A pilot study was conducted in 15 patients from each clinic.

The appropriateness of the standardized data collection form was tested if it is able to capture the relevant data.

The feasibility of the study is ensured as all the relevant data was available from the patients records.
• One quality measure of anticoagulation management is assessing how well the patient’s intensity of anticoagulation is maintained within the therapeutic range.

  Schmitt L. et al. 2003

• Primary outcome measure
  The control of INR per therapeutic INR range and per expanded therapeutic INR range
• A systematic review recommended that ≥ 2 outcome measures should be reported in order to monitor INR determinations and quality of dosing advice. These measures include clinical event rates.  

  
  **Wan Y. et al 2008**

• Secondary outcome measure  
  Combined incidence of adverse events  
  (thromboembolic and hemorrhagic events).
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Taipei International Convention Center in Taipei, Taiwan.

RESULTS & DISCUSSION
<table>
<thead>
<tr>
<th>Age</th>
<th>UMC</th>
<th>PMAC</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>64.1 ± 11.9</td>
<td>63.2 ± 13.0</td>
<td>$p &gt; 0.05$ (0.6)</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Male</td>
<td>Female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>52.2</td>
<td>47.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>50</td>
<td>$p &gt; 0.05$ (0.7)</td>
</tr>
<tr>
<td>Race (%)</td>
<td>Malay</td>
<td>Chinese</td>
<td>Indian</td>
</tr>
<tr>
<td></td>
<td>54.3</td>
<td>30.4</td>
<td>14.1</td>
</tr>
<tr>
<td></td>
<td>57.6</td>
<td>35.9</td>
<td>4.3</td>
</tr>
</tbody>
</table>

$n = 92$ patients in each arm
## Patient Demographics

<table>
<thead>
<tr>
<th>Indications for Warfarin (%)</th>
<th>UMC</th>
<th>PMAC</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation</td>
<td>87</td>
<td>76.1</td>
<td>p &gt; 0.001 (0.152)</td>
</tr>
<tr>
<td>Mech.Valve Replacement</td>
<td>2.2</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>A valve Replacement</td>
<td>1.1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Deep Vein Thrombosis</td>
<td>1.1</td>
<td>6.5</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>8.7</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Concurrent Diseases (%)</td>
<td>94.6</td>
<td>91.3</td>
<td>p &gt; 0.05 (0.388)</td>
</tr>
<tr>
<td>Concurrent Medications (%)</td>
<td>94.6</td>
<td>90.3</td>
<td>p &gt; 0.05 (0.266)</td>
</tr>
</tbody>
</table>
Clinical Outcomes

Percentage of INR within target range between UMC and PMAC

<table>
<thead>
<tr>
<th>Time in therapeutic range (% INR)</th>
<th>Type of target range</th>
<th>UMC</th>
<th>PMAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>Usual</td>
<td>48.3%</td>
<td>65.1%</td>
</tr>
<tr>
<td>10%</td>
<td>Expanded</td>
<td>66.1%</td>
<td>79.3%</td>
</tr>
</tbody>
</table>

p < 0.05 (<0.001)

n = 92 patients in each arm
Comparison of Relative Risks of Major/Total Bleeding: Non RCT Study vs Kuala Lumpur Hospital Study
Adverse events

Admission rates per 100 person year: UMC vs PMAC

p < 0.05
(0.005)
Comparison of average clinic visits between UMC and PMAC

<table>
<thead>
<tr>
<th></th>
<th>UMC</th>
<th>PMAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>11.2</td>
<td>7.9</td>
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</tbody>
</table>

p < 0.05 (0.005)
Conclusion

• PMAC provided a significantly better anticoagulation care than usual medical care both in terms of clinical outcomes and adverse outcomes. The PMAC with physician advisory has been successfully implemented in Kuala Lumpur Hospital.

• The next step in the research is to assess the cost effectiveness of the PMAC in comparison to the usual medical care.
Limitations

• Unable to obtain the estimated sample size due to a temporary policy change in the department where patients were accepted into the PMAC only after 3 months of usual medical care.

• Admission and adverse event recording could only be based on information available in the patients record book.

• Study was not designed to obtain mortality data.
Acknowledgement

• Dawn AC Software

• KLH - All the departments involved in the study.

• Ministry of Health, Malaysia (Pharmaceutical Services Division, Training Division)
References


THANK YOU