Epidemiology of diabetic patients: The latest results from a large observational trial focused on diabetes mellitus

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Disclosure

Speaker name:
Enrico Maria Marone

I do not have any potential conflict of interest
In diabetic patients the risk of PAD is 2-4 times higher than in not diabetic population.

(Lee AJ et al. BR J Haematol. 1999)
ORME - PAD: introduction

In 2014 5.5% of Italian population suffers from diabetes (ISTAT)

Source: ISTAT data, ISS elaboration.
ORME - PAD: aim of the study

• Select the diabetic population with PAD

• Epidemiological description and evaluation of direct medical costs
Materials and methods

DIABETIC POP: 2000-2010

N ≈ 566,000 subjects

Average annual incidence: Tot: 5.5x1,000
F: 5.1 , M: 5.9

Prevalence 2010:
Tot: 4.4 x 100
F: 3.8 , M: 4.5

Criteria 1: code ticket exemption for diabetes or two prescription A10XXX within 1 year or hospitalization for 250.xx
Materials and methods

**Criteria 1:**
- **DIABETIC POP: 2000-2010**
  - N ≈ 566,000 subjects
  - Average annual incidence:
    - Tot: 5.5 x 1,000
    - F: 5.1, M: 5.9
  - Prevalence 2010:
    - Tot: 4.4 x 100
    - F: 3.8, M: 4.5

**Criteria 2:**
- **DIABETIC POP. WITH PAD 2002-2009**
  - N ≈ 18,000 subjects
  - Average annual incidence:
    - Tot: 4.8 x 100
    - F: 4.0, M: 5.6
  - Prevalence 2009:
    - Tot: 25.2 x 100
    - F: 20.1, M: 25.1

**Criteria 2:** hospitalization (main and secondary diagnosis) and procedure (vasc/amp)
## Results

**STUDY POP.**

<table>
<thead>
<tr>
<th>DIABETIC POP. WITH PAD 2002-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>N ≈ 18,000 subjects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>N (%)</th>
<th>Middle age (Years (SD))</th>
<th>Median age (Years (min-max))</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>7,122 (39)</td>
<td>76 (10)</td>
<td>77 (40-102)</td>
</tr>
<tr>
<td>M</td>
<td>11,222 (61)</td>
<td>70 (10)</td>
<td>71 (40-98)</td>
</tr>
<tr>
<td>Totale</td>
<td>18,344 (100)</td>
<td>72 (10)</td>
<td>73 (40-102)</td>
</tr>
</tbody>
</table>

- 61% male vs 39% female
- Middle age at index date 72 yo
- Middle age at index date higher in females: hormonal protective (Dormandy JA, J Vasc Surg 2000)
Results

<table>
<thead>
<tr>
<th>Gender</th>
<th>N (%)</th>
<th>% comorbidities ≥ 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>7,122</td>
<td>29 %</td>
</tr>
<tr>
<td>M</td>
<td>11,222</td>
<td>32 %</td>
</tr>
<tr>
<td>Total</td>
<td>18,344</td>
<td>31 %</td>
</tr>
</tbody>
</table>

- Epidemiology:
  - M higher percentage of ≥ 3 comorbidities than F (at index date for PAD)
Results

Distribuzione % delle comorbidità

- Malattia Cardiaca: 50%
- Malattia Cerebrovascolare: 33%
- Malattia Polmonare Ostruttiva Cronica: 20%
- Malattia Renale: 17%
- Tumore: 14%
- Malattia Vascolare Periferica: 5%
- Malattia del Fegato: 5%
- Ulcera Peptica: 4%
- Emplegia/Paraplegia: 4%
- Malattia Reumatica: 2%
- AIDS: 0%
Results

### STUDY POP.

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>N (%)</th>
<th>% MALE</th>
<th>Middle age Years (SD)</th>
<th>Median age years (min-max)</th>
<th>% with CCI&gt;3</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO PROCEDURE</td>
<td>10,267(56)</td>
<td>56</td>
<td>73 (10)</td>
<td>74 (40-102)</td>
<td>32</td>
</tr>
<tr>
<td>VASCULARIZATION</td>
<td>5,156(28)</td>
<td>70</td>
<td>71(9)</td>
<td>72 (40-100)</td>
<td>29</td>
</tr>
<tr>
<td>MINOR AMP.</td>
<td>1,566(9)</td>
<td>68</td>
<td>71(11)</td>
<td>72 (40-102)</td>
<td>29</td>
</tr>
<tr>
<td>MAJOR AMP.</td>
<td>1,355(7)</td>
<td>57</td>
<td>75(10)</td>
<td>76 (40-99)</td>
<td>28</td>
</tr>
<tr>
<td>Total</td>
<td>18,344(100)</td>
<td>61</td>
<td>72(10)</td>
<td>73 (40-102)</td>
<td></td>
</tr>
</tbody>
</table>

1. 56% of population without procedure
2. NO PROC is the older group, with more comorbidities

NB: 75% of diabetic population with PAD is asymptomatic (Review Jude 2010)
Results

Epidemiology: **PAD** survival at index date for PAD
Results

Mortality adjusted to the same conditions (Cox Model)

- Years from index date
- PAD → +7%
- M → +20% F
- CCI≥3 → 2 times
Vascularization group
Vascularization group
Minor amputation group
Minor amputation group

KM survival estimates

AMP.MINORI

Probability of survival

Number at risk

1 AMP.MIN. 531 432 331 258 183 125 73 36
1° AMP.MIN. + altro 359 303 247 206 150 106 68 40
1° VASC + altro 450 378 305 239 168 123 77 39
Major amputation group
Major amputation group
Average cost per observation period (9 years) ≈ 35000 €
(I.C. 95%: 33308-37625€)
Costs

Cost type distribution of mean cost
N=18,344

<table>
<thead>
<tr>
<th>Years from index date</th>
<th>Hospitalization</th>
<th>Outpatient</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR -1</td>
<td>19</td>
<td>9</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 1</td>
<td>21</td>
<td>82</td>
<td>75%</td>
</tr>
<tr>
<td>YEAR 2</td>
<td>61</td>
<td>65</td>
<td>13%</td>
</tr>
<tr>
<td>YEAR 3</td>
<td>63</td>
<td>63</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 4</td>
<td>63</td>
<td>64</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 5</td>
<td>64</td>
<td>62</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 6</td>
<td>64</td>
<td>64</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 7</td>
<td>64</td>
<td>64</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 8</td>
<td>64</td>
<td>64</td>
<td>1%</td>
</tr>
<tr>
<td>YEAR 9</td>
<td>64</td>
<td>64</td>
<td>1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years from index date</th>
<th>N. patients</th>
<th>€/patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR 1</td>
<td>18,344</td>
<td>5,884</td>
</tr>
<tr>
<td>YEAR 2</td>
<td>18,344</td>
<td>14,085</td>
</tr>
<tr>
<td>YEAR 3</td>
<td>15,798</td>
<td>6,754</td>
</tr>
<tr>
<td>YEAR 4</td>
<td>13,130</td>
<td>6,258</td>
</tr>
<tr>
<td>YEAR 5</td>
<td>10,601</td>
<td>6,281</td>
</tr>
<tr>
<td>YEAR 6</td>
<td>8,309</td>
<td>6,257</td>
</tr>
<tr>
<td>YEAR 7</td>
<td>6,133</td>
<td>6,043</td>
</tr>
<tr>
<td>YEAR 8</td>
<td>4,293</td>
<td>6,062</td>
</tr>
<tr>
<td>YEAR 9</td>
<td>2,637</td>
<td>5,996</td>
</tr>
<tr>
<td></td>
<td>1,292</td>
<td>4,565</td>
</tr>
</tbody>
</table>
Conclusions

- DWH - DENALI
  - Picture of disease burden, currently absent in literature
  - Identification of 18,344 diabetic subjects with PAD
  - Evaluation of incidence, prevalence, survival and costs.

- Ongoing studies
  - Insight on survival after treatment (rivascularization / minor amputation)
  - Data comparison with the period 2010-2015
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