Nuovi trend nel panorama emodialitico internazionale

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Outline

• An introduction to the DOPPS
• Trends in hemodialysis treatment characteristics: association with outcomes
  – Treatment time
  – Kt/V
  – Vascular access
  – HDF use
Dialysis Outcomes and Practice Patterns Study (DOPPS)

- International prospective cohort study of hemodialysis patients and dialysis units practices
- Uniform international data collection
- Goal: Identify HD practice patterns associated with improved patient outcomes (adjusted for patient mix)
- Coordinated by the Arbor Research Collaborative for Health (Ann Arbor, MI USA)
DOPPS Sampling Protocol

**Goal:** A representative sample of dialysis facilities and patients from each country

**Methodology**

- Randomized selection among all facilities
- Exclude small facilities (< 25 in-center HD pts, affects ≤ 5% of HD patients in a country)
- Random selection stratified to ensure proportional representation by geographic region and facility types within each country
## DOPPS History

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Countries:</strong></td>
<td>7</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td><strong>Facilities:</strong></td>
<td>308</td>
<td>322</td>
<td>300</td>
<td>382</td>
</tr>
<tr>
<td><strong>Census Pts:</strong></td>
<td>&gt;50,000</td>
<td>&gt;43,000</td>
<td>&gt;50,000</td>
<td>&gt;54,000</td>
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<tr>
<td><strong>Sample Pts:</strong></td>
<td>&gt;17,000</td>
<td>&gt;12,800</td>
<td>&gt;11,300</td>
<td>&gt;15,000</td>
</tr>
<tr>
<td><strong>Focus:</strong></td>
<td>Cross-sectional, longitudinal, representative</td>
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<td></td>
<td>Comorbidities, medications, labs, QoL</td>
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<tr>
<td><strong>Additions:</strong></td>
<td>Cross-sections annually</td>
<td>+ incident &amp; depression</td>
<td>+ process of care &amp; nutrition</td>
<td>+3x/yr cross-sections, special study “modules”</td>
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<tr>
<td><strong>Outcomes:</strong></td>
<td>Quality of Life, Events, Hospitalizations, Mortality</td>
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</table>

* Japan, US, Europe (France, Germany, Italy, Spain, UK) + Australia, Belgium, Canada, New Zealand, Sweden

** Includes oversampling of small, rural, independent facilities in US
~ 382 randomly selected facilities stratified by unit type and geographic region

Japan (60 facilities)

Europe (140 facilities)

Canada & US (120 facilities)

Australia & New Zealand (20 facilities)
Dialysis Outcomes and Practice Patterns Study

The DOPPS Annual Report

www.DOPPS.org/AnnualReport
Age $\geq 75$ Years, Trends by Country
– DOPPS 2-4 Sample Patients* (2002-2010) –

% of Patients $\geq 75$ years

Non-European Countries

European Countries

Study Year

Study Year

*Initial prevalent cross-sections
Diabetes (as comorbidity) Trends by Country
– DOPPS 2-4 Sample Patients* (2002-2010) –

% of Patients

Non-European Countries

European Countries

*Initial prevalent cross-sections
Mortality Rate Trends by Country
– DOPPS 1-4 Patients* (1999-2010) –

Mortality Rate (per 100 pt. yrs)

**Non-European Countries**

**European Countries**

* Among patients in initial prevalent cross-section of each phase in facilities with at least 1 year of follow-up
Mortality Rate Trends by Region
– DOPPS 1-4 Patients* (1999-2010) –

Mortality Rate (per 100 pt. yrs)

- ANZ
- North America
- Europe
- Japan

* Among patients in initial prevalent cross-section of each phase in facilities with at least 1 year of follow-up
Dialysis Treatment Time and Patient Outcomes
Treatment Time Trends by Country
– DOPPS 2-4 Sample Patients* (2002-2010) –

Mean Treatment Time (min)

**Non-European Countries**
- ANZ
- JP
- CA
- US

**European Countries**
- FR
- BE
- SP
- IT
- UK
- GE
- SW

*Initial prevalent cross-sections
# Treatment Time Distribution Trends by Country

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**DOPPS 2-4 Sample Patients** *(2002-2010)*

<table>
<thead>
<tr>
<th>% of Patients</th>
<th>270+ min</th>
<th>240 to 269 min</th>
<th>210 to 239 min</th>
<th>&lt; 210 min</th>
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</thead>
</table>

| Phase | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 | 2 | 3 | 4 |
| ANZ   | 4 | 3 | 2 | 17| 15| 15| 14| 14| 8 | 3 | 5 | 2 | 11| 13| 13| 23| 3 | 6 | 6 | 14| 14| 14| 9 | 11| 13| 13| 4 | 3 | 2 |
| BE    | 54| 62| 54| 11| 9 | 9 | 7 | 7 | 7 | 12| 24| 38| 38| 51| 48| 51| 30| 29| 23| 14| 19| 15| 6 | 11| 13| 13| 23| 3 | 6 |
| CA    | 56| 62| 52| 69| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| FR    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| GE    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| IT    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| JPN   | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| SP    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| SW    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| UK    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |
| US    | 56| 70| 70| 62| 68| 69| 62| 24| 14| 12| 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | 5 | 4 | 5 | 5 |

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*Initial prevalent cross-sections*
Mean Facility % Patients with Treatment Time < 210 min, by Country (2009-2011)

*Cross-section, restricted to facilities with ≥ 8 patients on dialysis > 1 yr & receiving HD 3X weekly.
Treatment Time and Mortality, Hospitalization
(Facility Practice-based Analysis)

- All-cause mortality
- Cardiovascular death
- Sudden death
- Any hospitalization
- Cardiovascular hospitalization
- Hospitalization due to CHF or fluid overload

Adjusted hazard ratio per 30 minute longer prescribed treatment time (95% CI)
Facility Mean TT and Odds of Patients Having PO₄ > 5.5 mg/dl

AOR of PO₄ > 5.5 mg/dl vs < 5.5 mg/dl

AOR=0.84 per 30 min longer facility mean TT, p=0.01

Facility Mean Treatment Time (minutes)

- <222: 1.63, p<0.0001
- 222-236: 1.25, p=0.07
- 236-247: 1.16, p=0.21
- >247: 1.00, Ref

* Patients on dialysis > 1 yr; adjusted for: age, sex, race, ethnicity, time on dialysis, 14 summary comorbidities, living status, height, weight, Kt/V, blood flow, residual renal function, and catheter use as access. Stratified by country, accounted for facility clustering; (n=7225).
Trends in Dialysis Dose Delivered
% of HD Patients with Single Pool Kt/V < 1.2
–DOPPS 4 (2009-2011)–

Among prevalent cross-section of patients on dialysis >1 year
Facility % of Patients with Kt/V < 1.2

Facility % patients* with Kt/V < 1.2

Percentile
95th
75th
50th
25th
5th

Facility % of Patients with Kt/V < 1.2 and All-Cause Mortality

Continuous HR: 1.10 per 20% higher facility % patients with Kt/V < 1.2

Adjusted for age, sex, vintage, weight, height, 12 summary comorbidities, facility mean Hgb, facility % phosphate > 5.5 mg/dL, facility % serum Calcium > 10 mg/dL; n=11,500 patients in DOPPS 1-3 with vintage > 1 year (excluding Japan); Facility % of patients with Kt/V < 1.2 in 3 categories: < 5% (reference), 5-<20%, ≥ 20%) – HR for each category plotted at the category mean % of patients with Kt/V < 1.2
Vascular Access Use
Vascular Access Distribution Trends by Country
– Non-DM, 18-70 yr old DOPPS 2-4 Sample Patients* (2002-2010) –

% of Patients

<table>
<thead>
<tr>
<th>Phase</th>
<th>ANZ</th>
<th>BE</th>
<th>CA</th>
<th>FR</th>
<th>GE</th>
<th>IT</th>
<th>JP</th>
<th>SP</th>
<th>SW</th>
<th>UK</th>
<th>US</th>
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<tr>
<td>2</td>
<td>8%</td>
<td>17%</td>
<td>80%</td>
<td>76%</td>
<td>61%</td>
<td>85%</td>
<td>89%</td>
<td>89%</td>
<td>93%</td>
<td>84%</td>
<td>75%</td>
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<tr>
<td>3</td>
<td>7%</td>
<td>17%</td>
<td>65%</td>
<td>61%</td>
<td>52%</td>
<td>76%</td>
<td>86%</td>
<td>77%</td>
<td>93%</td>
<td>75%</td>
<td>70%</td>
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<td>4</td>
<td>11%</td>
<td>14%</td>
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<td>8%</td>
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*Initial prevalent cross-sections
Vascular Access: Mortality Risk Facility Based Model

RR of Death among Facility Patients per 20% more facility use of indicated access type

<table>
<thead>
<tr>
<th>Access Type</th>
<th>RR</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Catheters</td>
<td>1.19</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Grafts</td>
<td>1.08</td>
<td>0.008</td>
</tr>
<tr>
<td>Fistulae</td>
<td>1.00</td>
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* DOPPS 1+2, 1996-2004; n=27,892; adjusted for age, gender, black race, yrs with ESRD, 14 comorbidity classes, weight, facility median treatment time, facility % serum Ca >10 mg/dl, facility % serum PO₄ >5.5 mg/dl, whether hosp unit, & accounted for facility clustering effects; stratified by study phase & region. Facility access use adjusted for facility case-mix.

Pisoni et al AJKD (2009)
Relative Risk (95% CI)

Infection-Related Hospitalization

RR=1.79 (p<0.0001) per 20% Higher Facility Catheter Use

RR=1.33 (p=0.008) per 20% Higher Facility Catheter Use

Reference:
Facility Case-mix Adjusted Catheter Use <9%

*DOPPS 1+2, 1996-2004; n=27,401; adjusted for age, gender, black race, yrs with ESRD, 14 comorbidity classes, weight, baseline Kt/V, serum calcium, serum PO₄, whether hosp unit, & accounted for facility clustering effects; stratified by study phase & region. Facility access use (%) adjusted for facility case-mix.

Pisoni et al AJKD (2009)
Higher Facility Graft Use Associated with Higher Risk of Infection-related Hospitalization

Facility Graft Use (%)
- 15 - 23
- 23 - 32
- 32 - 50
- 50 +

Infection-Related Hospitalization
RR=1.11 (p=0.008) per 20% Higher Facility Graft Use

Vascular Access Infection-Related Hospitalization
RR=1.29 (p<0.0001) per 20% Higher Facility Graft Use

Reference:
Facility Case-mix Adjusted Graft Use <15%

*DOPPS 1+2, 1996-2004; n=27,401; adjusted for age, gender, black race, yrs with ESRD, 14 comorbidity classes, weight, baseline Kt/V, serum calcium, serum PO₄, whether hosp unit, & accounted for facility clustering effects; stratified by study phase & region. Facility access use (%) adjusted for facility case-mix.

Pisoni et al AJKD (2009)
Differences in Facility Vascular Access Explain Much of the Case-mix Adjusted Mortality Difference Between US and EUR*

All models were adjusted for age, gender, race, time on dialysis, 14 summary comorbid conditions, weight, unit type, facility median treatment time, facility % pts with serum phos > 5.5 and serum Ca> 10 mg/dl, and stratified by study phase; accounted for facility clustering effects. DOPPS 1 + 2; n=24,398; *EUR=France, Germany, Italy, Spain, and UK.

Pisoni et al AJKD (2009)
Hemodiafiltration: Trends & Outcomes
Hemodiafiltration Trends by Country
– DOPPS 1-4 Sample Patients* (1996-2010)

% of Patients

Study Phase (years)

1 (1996-2000)
2 (2002-2004)
3 (2005-2008)
4 (2009-Present)

*Initial prevalent cross-sections who dialyzed 3 times/wk with vintage ≥3 months; DOPPS 4 data are preliminary; ANZ, BE and SW did not participate in DOPPS phase 1
Facility % of Patients on HDF, by Phase and Country

Facility % of Patients

ANZ  BE*  FR  GE  IT  SP*  SW*  UK*  JP†  All

Percentile
95th
75th
50th
25th
5th

Initial prevalent cross-sections who dialyzed 3 times/wk with vintage ≥3 months
* p-value <0.05 for test for trend for HDF use over time; †HDF was not used in Japan during DOPPS phases 1 and 2.
Association of Modality with Mortality and Hospitalization

Adjusted for age, gender, race, vintage, BMI and catheter use, 13 comorbidities, hemoglobin, albumin and single pool Kt/V, dialysate flow and blood flow; stratified by phase and region and accounted for facility clustering: Region 1: UK, Sweden, Germany and Belgium; Region 2: France, Australia-New Zealand, Spain, and Italy
Association of Modality with Inflammatory Markers

**Patient model**

Ref = High-Flux HD

- Ferritin >800 ng/mL
- CRP >10 mg/L*
- WBC > 8000 mL
- Serum albumin <3.5 g/dL

**Instrumental Variable analysis**

Ref = High-Flux HD

- Low-vol. HDF
- High-vol. HDF
- Low-flux HD

Odds Ratio (95% CI)

All models are adjusted for age, gender, race, vintage, BMI, catheter use, facility type, 13 comorbidities, albumin (except for model with albumin as outcome), prescribed blood flow rate, prescribed dialysate flow rate, phase, region and accounted for facility clustering; Region 1: UK, Sweden, Germany and Belgium; Region 2: France, Australia-New Zealand, Spain, and Italy

*DOPPS 3 only
GRAZIE!

• Al personale medico ed infermieristico dei centri DOPPS

• Ai pazienti partecipanti

...per rendere il DOPPS possibile!