


Importance of clinical research in hematology



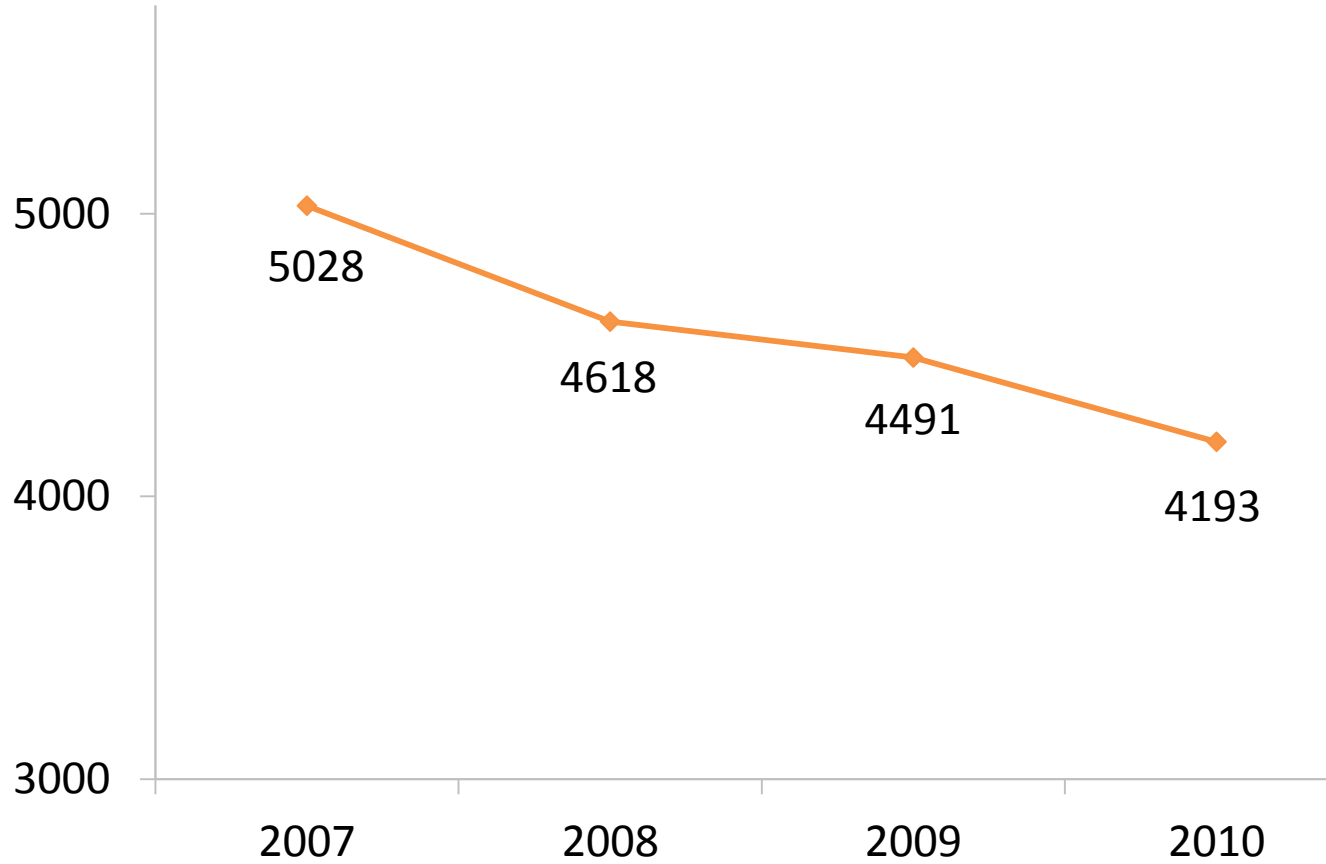
Marc André

An iPad is shown from a top-down perspective, displaying a quote on its screen. The iPad has a silver bezel and a black front face. The screen is dark gray with white text. The quote is centered and reads: « Innovation is a choice because you have a burning passion for something». The name 'Steve Jobs' is written in the bottom right corner of the screen. The iPad's home button is visible on the left side of the bezel.

« Innovation is a choice
because you have a burning
passion for something»

Steve Jobs

Diminution of clinical trials applied for in the EU



“The system for conducting clinical trials in the United States is approaching a state of crisis”

- cumbersome procedures
- excessive bureaucracy
- poor coordination
- failure to complete 40% of the trials

My task today:

- Our treatment must rely on evidence-based medicine.
- Clinical trials are the only way to demonstrate better treatments.

Main message

- Clinical research is the only way to progress.
- But has become more complicate, time consuming and... expensive.
- Therefore, all parties need to collaborate and make an additionnal effort.

Preview

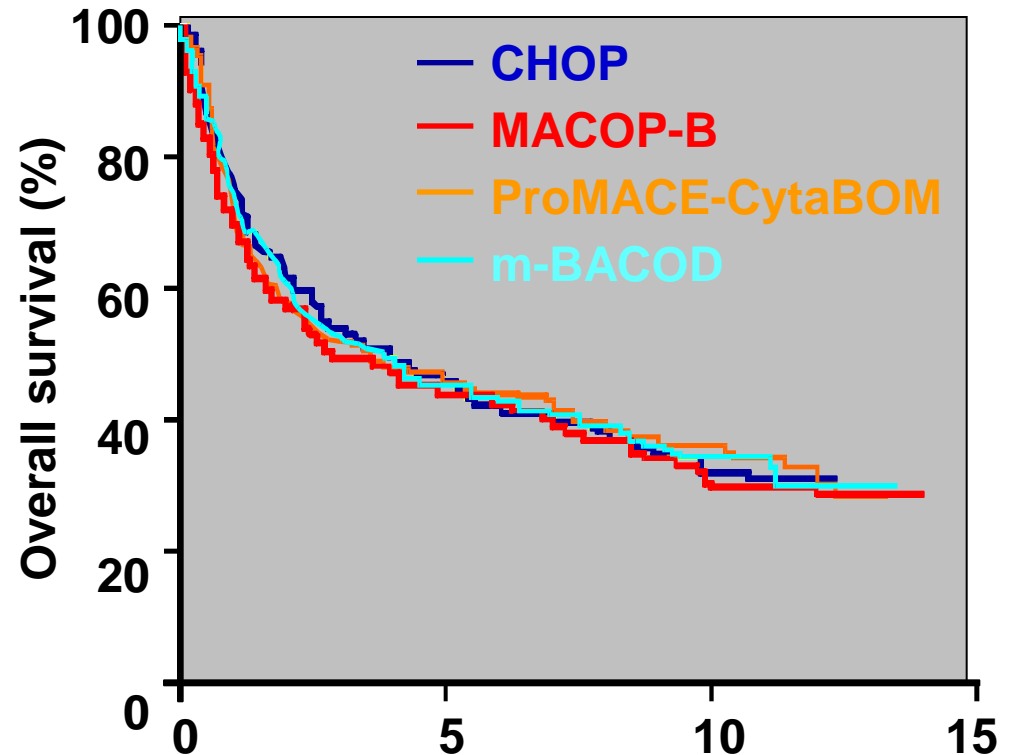
- **The case of lymphoma therapy.**
- Patients.
- Doctors.
- Nurses.

The case of lymphoma therapy

- 1980 : CHOP was the standard of care (30%)
- Phase II trials with intensified chemotherapy (mBACOD, ProMACE-CytaBOM, MACOP-B)
- Showed an improvement of outcome (55-65%)

In DLBCL, CHOP was a good standard...

- It was easy to use
- It gave reproducible results
- Intensified chemotherapy are not better



... CHOP remains standard but we can improve

LNH 98.5 study : Design

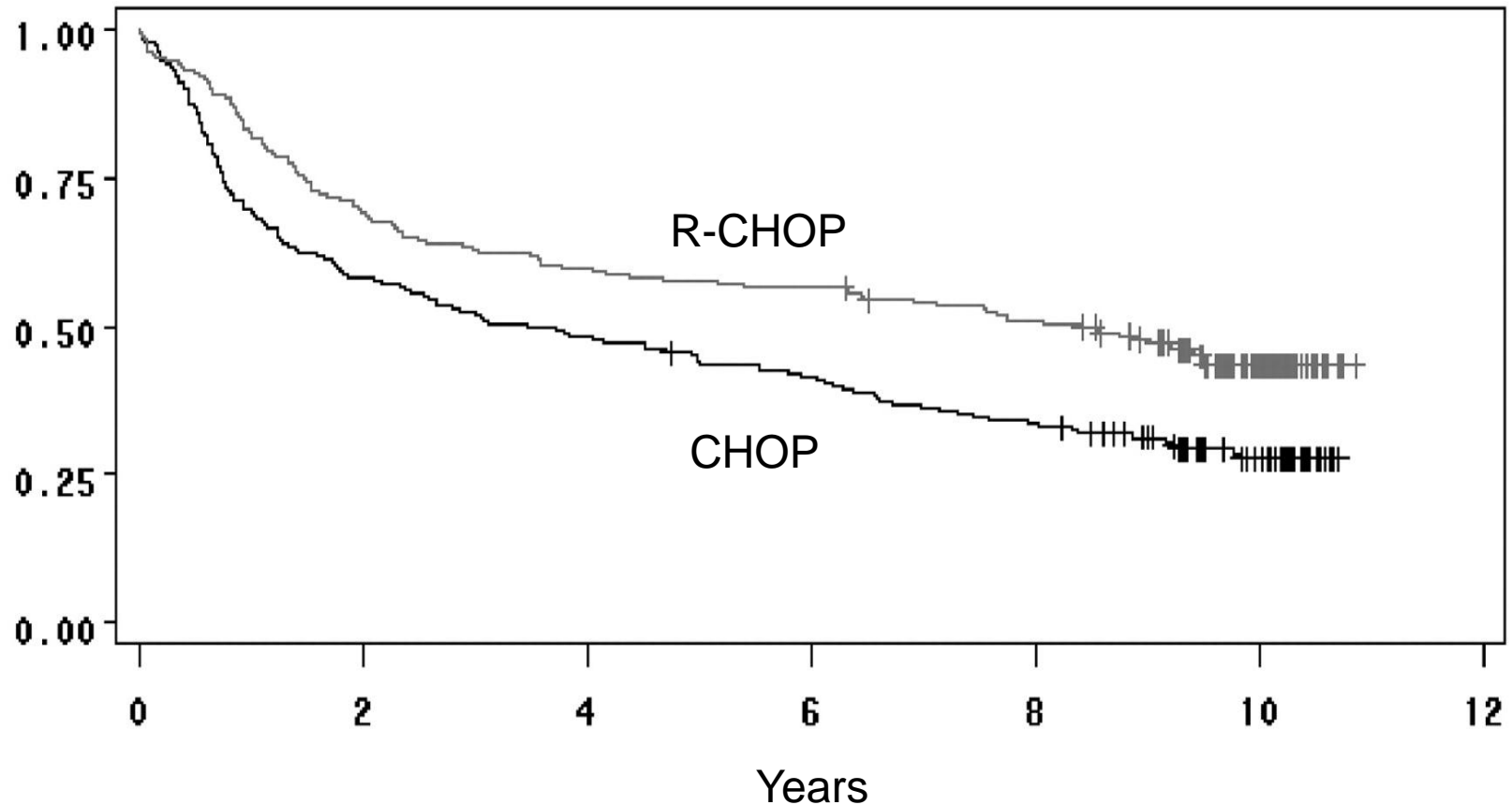
- Diffuse large B cell lymphoma
- Age 60–80 years
- No prior treatment
- PS 0–2
- Stage II–IV

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Rituximab
+
CHOP
q3wk x 8

CHOP
q3wk x 8

Overall survival is superior in patients treated With R-CHOP compared to CHOP



The case of lymphoma therapy

- 1980 : CHOP was the standard of care
- Phase II trials showed an improvement of outcome with intensified chemotherapy
- 1993: Phase III randomised trial : CHOP was still the standard of care
- 2002: Phase III randomised trials : R-CHOP become the reference.

Preview

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Informations « caught » by the patient (Phase I)

What doctors believe they said and what patients believe they heard

Additional effort	85%
Goal trial	83%
Benefit	73%
Unknown side effects	46%
Voluntary	43%
Right to stop	35%
Prognosis	21%

Survey on 262 informed consent

Personnal benefit	2%
Chance of prolonged survival	16%
Chance of tumor response	34%
Unknown side effects	83%
Serious Harms	91%
Right to stop	97%

Patients: non participation

- I will be a guinea pig
- If I don't get into the treatment arm, I will get sugar pill.
- Consent forms only protects the legal interest of researchers, institutions and drug companies.

Preview

- The case lymphoma therapy.
- Patients.
- **Doctors.**
- Nurses.



Preview

- The case lymphoma therapy.
- Patients.
- Doctors.
- **Nurses.**

Nurses

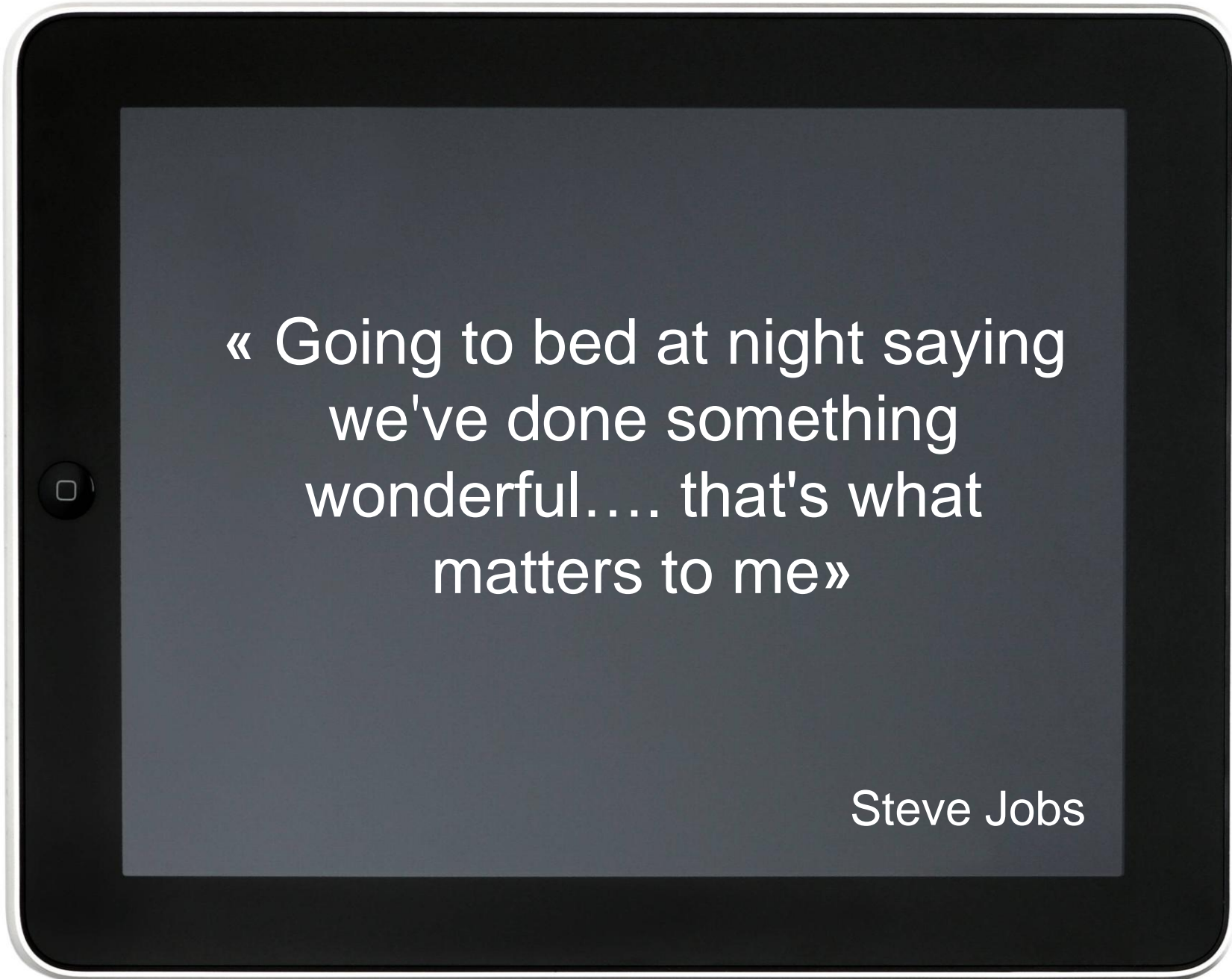
- Examined 455 nurses general attitudes toward cancer clinical trial
- Were comfortable discussing treatment options with their cancer patients ($p=0.001$).
- Had adequate time during patients' visit to explain clinical trials ($p=0.008$).
- They believed that patients in clinical trials were receiving the best medical treatment ($p=0.019$).

Review

- Improvement in the treatment of NHL occurred with clinical trials (Phase III)
- Performing randomised trial is an additional effort for:
 - The patient
 - The doctors
 - The nurses

Conclusions

- The number of clinical trials in Europe and in US is diminishing.
- Clinical trials are the only way to bring better treatments to our patients.
- Participation to clinical research in hematology requires an extra workload.

A black tablet with a silver bezel is shown. The screen displays a quote in white text on a dark grey background. The quote is: « Going to bed at night saying we've done something wonderful.... that's what matters to me». The name 'Steve Jobs' is written in the bottom right corner of the screen. The tablet has a circular home button on the left side.

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**27th General Meeting
of the Belgian Hematological Society**



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